FILED KURT RAMLO (SBN 166856) LEVENE, NEALE, BENDER, YOO & BRILL L.L.P. 10250 Constellation Boulevard, Suite 1700 2018 JUL 23 PM 3: 09 Los Angeles, California 90067 Telephone: (310) 229-1234 Facsimile: (310) 229-1244 3 4 KR@LNBYB.com Gregory M. Utter * (OH Bar No. 0032528) Joseph M. Callow, Jr. * (OH Bar No. 0061814) 51 COURT 4612 KEATING MUETHING & KLEKAMP PLL 6 One East Fourth Street 71 **Suite 1400** Cincinnati, Ohio 45202 Phone: (513) 579-6400 Fax: (513) 579-6457 2018 6 111 8 9 **DIA9** gmutter@kmklaw.com, jcallow@kmklaw.com Joel D. Hesch * (DC Bar No. 421822) THE HESCH FIRM, LLC 10 11 3540 Ridgecroft Dr. Lynchburg, Virginia 24503 Phone: (434) 229-8677 12 joel@howtoreportfraud.com 13 ATTORNEYS FOR RELATORS 14 * Pro hac vice applications forthcoming 15 UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA 16 WESTERN DIVISION CV18-06352-004/MAX 17 Case No. 18 UNITED STATES OF AMERICA and the STATES OF ALASKA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW HENCEY NEW MENTANA, NEVADA, NEW HAMPSHIRE, NEW MENTANA, NEVADA, NEW MENTANA, NEW MENTAN 19 COMPLAINT FOR VIOLATIONS OF 20 THE FEDERAL AND STATE FALSE JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, and the DISTRICT OF COLUMBIA 21 CLAIMS ACTS; DEMAND FOR JURY 22 TRIAL 23 FILED UNDER SEAL NICHOLAS FINCH and NICHOLAS SACCOMANNO **PURSUANT TO 31** 24 U.S.C. § 3730(B)(2) Plaintiffs/Relators, 25 DO NOT ENTER VS. ON PACER NIHON KOHDEN CORPORATION, NIHON KOHDEN 26 DO NOT PLACE AMERICA, INC., and NIHON KOHDEN ORANGEMED, 27 IN PRESS BOX INC. 28 Defendants.

Relators Nicholas Finch ("Mr. Finch") and Nicholas Saccomanno ("Mr. Saccomanno") (collectively, the "Relators"), by and through the undersigned counsel, and on behalf of the United States of America ("United States") and the States of Alaska, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, State of Washington, and the District of Columbia (collectively, the "States"), hereby allege as follows:

I. <u>INTRODUCTION</u>

- 1. This is a *qui tam* action by Relators, filed on behalf of the United States and States, against Nihon Kohden Corporation ("NK Corporation"), Nihon Kohden America, Inc. ("NK America") and Nihon Kohden OrangeMed, Inc. ("NK OrangeMed") (collectively, "Nihon Kohden" or "Defendants") for using, making, presenting, and causing to make, use, or present false statements and claims to the governments of the United States and States (collectively, the "Government") in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq.* and applicable State law.
- 2. This case is about the fraudulent practices occurring at Nihon Kohden—an international giant in the medical device industry earning hundreds of millions in global revenue each year. In 2017 alone, Nihon Kohden generated \$18.9 billion yen (approximately \$170 million USD) in medical device sales in just the Americas—primarily in the United States. In addition, in 2016, NK America was also awarded a \$35 million federal contract with the U.S. Department of Defense for

¹ This figure is from Nihon Kohden's 2017 annual report which is consolidated for NK Corporation and its subsidiaries, including NK America. *Nihon Kohden Report* 2017 at 18, https://www.nihonkohden.com/ir/library/pdf/NKreport2017E.pdf (last visited July 3, 2018).

patient monitoring equipment.²

- 3. The fraud alleged herein is straightforward. Since at least 2012—but upon information and belief, as early as 2008—Nihon Kohden has unlawfully marketed, distributed and sold various adulterated/misbranded/off-label patient monitoring medical devices without the necessary premarket government approval. More specifically, Nihon Kohden has a corporate-wide practice and culture of entirely ignoring the Food and Drug Administration ("FDA")'s 510(k) clearance process. And since the arrival of NK America's current CEO in 2014, Dr. Wilson Constantine, this fraud has continued to worsen and grow each year.³
- 4. This fraud involves multiple patient monitoring devices, including, but not limited to, Nihon Kohden's: (i) BSM-1700 monitor(s); (ii) BSM-3500 monitor(s); (iii) tele-transmitter(s); and (iv) remote network station(s) ("RNS(s)") (all adulterated/misbranded/off-label products together, the "Monitoring Devices"). All of these Monitoring Devices are adulterated/misbranded/off-label and have been adulterated/misbranded/off-label for a number of years, but were nonetheless

² Contract No. SPM2D1-12-D-8300 is a one-year base contract with eight one-year option periods for patient monitoring equipment, to be used by the Air Force, Army, Navy, Marine Corps, and federal civilian agencies. *Contracts: Defense Logistics Agency*, U.S. DEP'T OF DEFENSE (Oct. 26, 2016), *available at https://www.defense.gov/News/Contracts/Contract-View/Article/987608/* (last visited July 5, 2018).

³ The current CEO of NK America—Dr. Wilson P. Constantine—was previously a vice president of OtisMed Corporation and Stryker Corporation in 2014, when OtisMed pleaded guilty and paid over \$80 million to resolve allegations that it violated FDA marketing clearance regulations and introducing adulterated medical devices into interstate commerce. *OtisMed Corporation and Former CEO Plead Guilty to Distributing FDA-Rejected Cutting Guides for Knee Replacement Surgeries: Corporation to Pay More than \$80 Million to Resolve Criminal and Civil Investigations*, U.S. DEP'T OF JUSTICE, U.S. Attorney's Office District of New Jersey (Dec. 8, 2014), *available at* https://www.justice.gov/usao-nj/pr/otismed-corporation-and-former-ceo-plead-guilty-distributing-fda-rejected-cutting-guides (last visited July 3, 2018).

5 6 7

8 9 10

11 12

13 14

15 16 17

18 19

20

21 22

23 24

25 26 27

28

marketed, distributed and sold by Nihon Kohden. Relators believe that over 50% of all of Nihon Kohden's devices are adulterated/misbranded/off-label, and that the particular devices discussed herein make up well over half of Nihon Kohden's annual revenue in the U.S.

- Rather than go through the proper FDA channels, Nihon Kohden side-5. steps the 510(k) clearance process altogether by simply adding an internal "letter to the file" ("LTF") to a different device that received 510(k) clearance years earlier. These internal LTFs are improper because the Monitoring Devices are significantly different from any previously-cleared devices and, therefore, require their own independent 510(k) clearance. For years, Nihon Kohden has purposely evaded this requirement in order to rush its adulterated/misbranded/off-label Monitoring Devices to market without being delayed by the FDA clearance process. Simply put, market demand and profits have superseded regulatory requirements for a number of years
- 6. Nihon Kohden has received multiple complaints from consumers regarding these Monitoring Devices. But because these devices are all adulterated/misbranded/off-label, Nihon Kohden never submitted any of these complaints to the FDA. Had it done so, it would have notified the FDA that it was marketing and distributing adulterated/misbranded/off-label devices—thereby blowing the whistle on itself. As a result, numerous consumer complaints go unreported each year. In fact, Nihon Kohden has even recalled several Monitoring Devices in response to consumer complaints. But once again, because these Monitoring Devices are all adulterated/misbranded/off-label and not filed with the FDA, these recalls go unreported as well.
- 7. Over the years, multiple employees, including Relators, have voiced concerns to corporate leadership about the internal LTF process and the adulterated/misbranded/off-label devices. To date, Nihon Kohden has purposely ignored and rebuked all such complaints. As a result, the fraud still continues to this

day.

8. Under the terms of the False Claims Act, this Complaint is to be filed *in camera* and under seal and is to remain under seal for a period of at least 60 days and shall not be served on Defendant until the Court so orders. The Government may elect to intervene and proceed with the action within the 60-day time frame, or within any extensions of that initial sixty-day period granted by the Court for good cause shown, after it receives both the Complaint and the statement of material evidence submitted to it.

II. NATURE OF THE ACTION

- 9. This is an action to recover treble damages and civil penalties arising from the fraudulent conduct of Defendants for using, making, presenting, and causing to make, use, or present false statements and claims to the Government in violation of the False Claims Act, 31 U.S.C. § 3729 et seq. and all applicable State laws (collectively, the "False Claims Act").
- 10. Under the False Claims Act, a private person may bring an action in federal district court for himself and for the United States and States, and may share in any recovery. 31 U.S.C. § 3730(b). That private person is known as a "Relator" and the action that the Relator brings is called a *qui tam* action.

III. JURISDICTION AND VENUE

- 11. This Court has subject matter jurisdiction to adjudicate this action under 28 U.S.C. §§ 1331 and 1345.
- 12. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because Defendants transact and have transacted business in this District.
- 13. Venue is proper in this District under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Defendants are located in and transact business in this District.

IV. THE PARTIES

- 14. The Relators bring this action on behalf of the United States, including its agency, the Department of Health and Human Services ("HHS"), its component, the Centers for Medicare & Medicaid Services ("CMS," formerly the Health Care Financing Administration ("HCFA")), and all other Government healthcare programs, such as Medicaid, TRICARE/CHAMPUS, Blue Cross/Blue Shield CHIP, and Veterans Administration ("VA").
- 15. The Relators also bring this action on behalf of all other United States agencies and departments, including the Department of Defense, the United States Army, the United States Air Force, the United States Navy, the United States Marine Corps., and all related agencies thereto.
- 16. The Relators also bring this action on behalf of the States of Alaska California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, and the District of Columbia, along with all state counterpart agencies to the federal agencies referenced above.
- 17. The Relators also bring this action on behalf of themselves, as permitted under the False Claims Act.
 - a. Relator Nicholas Finch is a citizen of the United States and a resident of the State of California who has spent the last six years in the patient monitoring industry. From 2013 to 2018, Mr. Finch worked at NK America as a Level 2 Project Manager where he was responsible for managing and developing for market release new product interfaces for Nihon Kohden's patient monitoring devices.
 - b. Relator Nicholas Saccomanno is a citizen of the United States and a resident of the State of California with 8 years at years of industry

- experience. Mr. Saccomanno worked at NK America as a Project Manager (from 2010 to 2013) and Senior Project Manager (from 2015 to 2018) where he led project development for patient monitoring devices for market release.
- 18. Mr. Finch and Mr. Saccomanno both discovered the allegations set forth herein while employed at NK America. Relators are original sources of these allegations, and have direct and independent knowledge of the information on which the allegations set forth in this Complaint are based.
- 19. Defendant Nihon Kohden Corporation is a Japanese corporation with its principal place of business at 1-13-4 Nishiochiai, Shinjuku-ku, Tokyo 161-8560, Japan. NK Corporation is a global manufacturer, developer, and distributor of medical electronic equipment, including electroencephalograms (EEGs), electromyography (EMG) measuring systems, electrocardiograms (ECGs or EKGs) and other patient monitors.
- 20. Defendant Nihon Kohden America, Inc. is a California corporation with its principal place of business located at 15353 Barranca Parkway, Irvine, California 92618. NK America is a subsidiary of NK Corporation. NK America develops, manufacturers, and distributes Nihon Kohden medical electronic equipment for patient monitoring throughout the North America region.
- 21. Defendant Nihon Kohden OrangeMed, Inc. is a California corporation with its principal place of business located at 1800 E. Wilshire Avenue, Santa Ana, California 92705. NK OrangeMed is a sales and research/development subsidiary of NK Corporation.

V. LEGAL FRAMEWORK

A. The False Claims Act

- 22. The False Claims Act ("FCA") imposes civil liability upon any person who:
 - (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
 - (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]

. . . .

- (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.
- 31 U.S.C. § 3729(a). The Affordable Care Act requires a person who has received an overpayment from the Government to report and return the overpayment within 60 days of identification, or the date that any corresponding cost report is due; and failure to report and return the overpayment is an obligation for purposes of the False Claims Act under 31 U.S.C. § 3729(a)(1)(G). See 42 U.S.C. § 1320a-7k(d).
 - 23. For purposes of the FCA, the terms "knowing" and "knowingly":
 - (A) mean that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and
 - (B) require no proof of specific intent to defraud.
- 31 U.S.C. § 3729(b). Effective November 2, 2015 (the date of enactment of the Federal Civil Penalties Inflation Adjustment Act, Improvements Act of 2015, Public Law 114-74, sec. 701 ("2015 Amendments")), the penalties increased from a minimum-maximum per-claim penalty of \$5,500 and \$11,000 to \$10,781 and \$21,563. The increased amounts apply to civil penalties assessed for violations occurring after November 2, 2015. Violations that occurred on or before November

2, 2015 are subject to the previous penalty amounts. On February 3, 2016, pursuant to the 2015 Amendments annual re-indexing of the FCA penalties for inflation, the civil penalties again increased to a minimum-maximum per-claim penalty of \$10,957 and \$21,916. As of January 19, 2018, the FCA penalties were again increased to the current minimum-maximum per-claim penalty of \$11,181 and \$22,363.

B. The Medicare Program

- 24. The Health Insurance for the Aged and Disabled Program, popularly known as the Medicare program, was created in 1965 as part of the Social Security Act ("SSA") to pay the costs of certain healthcare services for eligible individuals. The Secretary of Health and Human Services ("HHS"), an agency of the United States whose activities, operations, and contracts are paid from federal funds, administers the Medicare program through the Centers for Medicare and Medicaid Services ("CMS"), a component of HHS.
- 25. Medicare is a 100% federally subsidized health insurance system for eligible Americans, including those aged 65 and older, certain disabled people, and certain people with chronic diseases who elect coverage. 42 U.S.C. § 1395c; see 42 U.S.C. §§ 1395j-1395w. To participate in Medicare, a provider must sign and file a Provider Agreement with CMS promising compliance with applicable statutes, regulations, and guidance. 42 U.S.C. § 1395cc; 42 C.F.R. § 412.23(e)(1). Medicare service providers have a legal duty to familiarize themselves with Medicare's reimbursement rules, including those delineated in the Medicare Manuals. Heckler v. Cmtv. Health Serv. of Crawford Co., Inc., 467 U.S. 51, 64–65 (1984).
- 26. Under Medicare Part B, providers are typically compensated for the services they provide to Medicare beneficiaries on a "fee-for-service" basis as determined by Medicare's fee schedule. 42 U.S.C. § 1395w-4. To obtain compensation, providers must deliver a compensable service, certify that the service was medically necessary for the health of the patient, certify that the service was

personally furnished by the physician (or under his or her immediate supervision), and determine the appropriate diagnosis and procedure code to describe the problem and service for billing.

- 27. In order to bill Medicare, a provider must submit a form called the CMS 1500. The form describes, among other things, the provider, the patient, the referring physician, the services provided by procedure code, the related diagnosis code(s), the dates of service, and the amounts charged. The provider certifies on the CMS 1500 claim that the information provided is truthful and that the services billed on the form were "medically indicated and necessary."
- 28. Reimbursement for Medicare claims is made by the United States through HHS. CMS is an agency of HHS and is directly responsible for the administration of the Medicare program. CMS, in turn, contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. *See* 42 U.S.C. § 1395u. Claims submitted for reimbursement are to be paid in accordance with the Social Security Act, Code of Federal Regulations, and Medicare Rules and Regulations promulgated by CMS.

C. The Medicaid Program

- 29. Medicaid is a joint federal-state program that pays for healthcare services for low-income individuals, including pregnant women, children, and parents and other caretaker relatives, as well as elderly and disabled individuals. As a result of the Affordable Care Act, each state had the option to expand eligibility for Medicaid beginning in calendar year 2014 to all nonelderly adults with income below 138 percent of the federal poverty guidelines.
- 30. Medicaid is jointly funded by state and federal governments. The federal government's share of each state's Medicaid spending, known as the Federal Medical Assistance Percentage ("FMAP"), is based upon the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Such share must be at least 50 percent, but no more than 83 percent, and historically has averaged

about 57 percent. In other words, the federal government guarantees to match at least \$1 in federal funds for every \$1 any individual state spends on its Medicaid program.

31. State Medicaid programs must comply with the minimum requirements set forth in the federal Medicaid statute to qualify for federal funding. 42 U.S.C. § 1396a. In order to receive reimbursement from Medicaid, a provider must submit a signed claims form to the state's Medicaid program, certifying that the information on the form is "true, accurate, and complete." 42 C.F.R. § 455.18. The provider further certifies that it "understand[s] that payment of this claim will be from federal and state funds, and that any falsification, or concealment of a material fact, may be prosecuted under federal and state laws." *Id*.

D. Regulation of Medical Devices

- 32. The Food & Drug Administration ("FDA") is a federal governmental agency responsible for protecting the health and safety of the public by assuring, among other things, that medical devices are safe and effective for their intended uses and that the labeling of such devices bear true and accurate information. Under the federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 301–397, the "FDCA"), the FDA regulates the manufacture, labeling, and shipment in interstate commerce of such devices.
- 33. Under the FDCA, every manufacturer of a device is required to obtain authorization from the FDA prior to marketing its devices, unless the device is a Class I or II device and the manufacturer can demonstrate that the device is "substantially equivalent" to another device already legally marketed in the United States.
- 34. To establish "substantial equivalence," the manufacturer must submit a Section 510(k) application to the FDA which establishes that the new device: (1) has the same intended use as a predicate device; and (2) the device either (a) has the same technological characteristics as the predicate, or (b) does not raise new

questions of safety or efficacy and demonstrates that the new device is at least as safe and effective as the old device. In order obtain Section 510(k) clearance, the device must have the same intended use as an existing, legally marketed device.

- 35. To be eligible for Medicare/Medicaid coverage, a product or device must be "reasonable and necessary" for the treatment of illness or injury or to improve functioning of a malformed body member. CMS has interpreted this "reasonable and necessary" standard to require that a product or device—at minimum—be safe and effective, which in turn, means that, unless exempt, it must have been approved or cleared for marketing by the FDA. Medical devices that lack approval from the FDA are not reimbursable. 42 C.F.R. § 411.15(o) and 405.211(c).
- 36. Federal regulations also provide that a manufacturer must submit a premarket notification submission, such as a 510(k) request, when "[t]he device is one that the person currently has in commercial distribution . . . but *that is about to be significantly changed or modified in design, components, method of manufacture, or intended use.*" 21 C.F.R. § 807.81 (emphasis added).
- 37. A device is "adulterated" if it is required to have, but does not have, FDA premarket approval for its intended use. The FDCA prohibits the introduction of adulterated medical devices into interstate commerce. 21 U.S.C. § 331(a).
- 38. A device is "misbranded" if the manufacturer of that device was required to file a 510(k) premarket notification with the FDA 90 days prior to introducing the device into interstate commerce and failed to do so. The FDCA prohibits the introduction of misbranded medical devices into interstate commerce. 21 U.S.C. § 331(a).
- 39. Adulterated devices and misbranded devices may not be introduced into commerce, and neither are eligible for use or reimbursement by Medicare, Medicaid, or any other health insurance program funded by the Government.

VI. FACTUAL ALLEGATIONS

- 40. Since at least 2012—but upon information and belief, as early as 2008—Nihon Kohden has unlawfully marketed, distributed and sold various adulterated/misbranded/off-label patient monitoring medical devices without the necessary premarket government approval. More specifically, Nihon Kohden has a corporate-wide practice and culture of entirely ignoring the FDA's 510(k) clearance process.
- 41. Rather than go through the proper FDA channels, Nihon Kohden sidesteps the 510(k) clearance process altogether by simply adding an internal "letter to the file" to another device that received 510(k) clearance years earlier. These internal LTFs are improper because the Monitoring Devices are significantly different from any previously-cleared devices and, therefore, require their own independent 510(k) clearance. For years, Nihon Kohden has purposely evaded this requirement in order to rush its Monitoring Devices to market without being delayed by the FDA clearance process. Simply put, market demand and profits have superseded regulatory requirements for a number of years.
- 42. By way of example, some of Nihon Kohden's most adulterated and misbranded devices include, but are not limited to: its: (i) BSM-1700(s); (ii) BSM-3500(s); (iii) tele-transmitter(s); and (iv) remote network station(s) ("RNS(s)"). These devices are further discussed below:

A. The BSM-1700 Bedside Monitor

- 43. Back in 2008, Nihon Kohden received 510(k) clearance for its BSM-6000 series bedside monitor on the basis that it was substantially equivalent to certain other Nihon Kohden predicate devices—namely, the BSM-5130A and the ORG-9700. A true and accurate copy of Nihon Kohden's marketing brochure for the BSM-6000 series bedside monitor is attached hereto as **Exhibit A**.
- 44. In 2011, Nihon Kohden introduced the BSM-1700. It is considered the world's smallest fully-featured patient monitor, and is one of Nihon Kohden's best-

selling devices. A true and accurate copy of Nihon Kohden's marketing brochure for the BSM-1700 is attached hereto as **Exhibit B**.

- 45. The BSM-1700 is a bedside monitor capable of serving as a WLAN transport monitor, standard transport monitor, stand-alone monitor, or an input unit for the BSM-6000 bedside monitor. When not being used as a stand-alone model or transport monitor, the BSM-1700 serves a host device to the BSM-6000 series. The BSM-1700 displays the patient's parameters on a screen, communicates the patient's data over a network, and charges the internal batteries of the BSM-1700. When the patient is transferred to a different location, the BSM-1700 disconnects from the 6000 series (which remains stationary) and goes with the patient to his or her next location. The BSM-1700 is considered the world's smallest fully featured transport monitor; and compared to the BSM-6000 series, had significant changes and modifications to its design, material, energy source, manufacturing process, and its intended use.
- 46. A comparative review of the BSM-1700 versus the BSM-6000 further illustrates the differences between these two monitoring devices. Such differences include, but are not limited to, differences in size, weight, resolution, power source, multi-functionality, user interface operations, internal software, and device hardware. A true and accurate copy of Nihon Kohden's "Bedside Monitor Specification Comparison," which outlines the differences between the BSM-1700 and BSM-600, is attached hereto as **Exhibit C**.
- 47. Given these significant changes and modifications, Nihon Kohden was required to file a premarket notification submission with the FDA seeking independent 510(k) clearance for the BSM-1700 device. Nihon Kohden was required to demonstrate how—despite these significant changes—the BSM-1700 was still substantially equivalent to the BSM-6000 series. To date, Nihon Kohden has failed to file any such submission. Instead, it simply filed an internal LTF against its original BSM-6000 series, and introduced the BSM-1700 into commerce without

any premarket clearance/approval.

- 48. Since the BSM-1700 was first introduced in 2011, the device has undergone additional software and hardware changes, each of which have been documented by additional internal LTFs against the original 6000 series. There are now nearly a dozen internal LTFs for the various changes made to the BSM-1700—all of which were applied against the original BSM-6000 series. Once again, the BSM-1700 to this day still has no independent clearance on its own.
- 49. Nihon Kohden knew that a new 510(k) submission was required for the BSM-1700, yet intentionally chose not to file one. For example, an internal email amongst Nihon Kohden personnel and leadership dated December 9, 2014, subject line titled "RE: Software upgrade: BWM-1700 VO1-10" states:

With these changes I am in agreement that the LTF is appropriate. I remain concerned however that this device needs a catch-up 510(k) as the original introduction of the device raises questions that we would find difficult to defend. The more changes we make to the device the more difficult it will be to indicate why the device does not have an independent clearance.

Nihon Kohden's CEO, Dr. Wilson Constantine, was copied on this email.

50. The BSM-1700 has now been on the market for several years and is used regularly by hospitals and healthcare providers throughout the United States. The BSM-1700 costs approximately \$7,560.00 to \$7,830.00. This is Nihon Kohden's highest selling device and is one of its greatest revenue generators.

B. The BSM-3500 Bedside Monitor Series

- 51. In 2014, Nihon Kohden introduced the BSM-3500—another bedside monitor that, like the BSM-1700, has an internal LTF filed against the BSM-6000 and lacks its own FDA clearance or approval. The BSM-35000 is an all-in-one bedside monitor specifically designed for ambulatory and specialty center use. A copy of Nihon Kohden's marketing brochure for the BSM-3500 is attached hereto as **Exhibit D**.
 - 52. Compared to the BMS-6000 series, the BSM-3500 had significant

changes and modifications to its design, material, energy source, manufacturing process, and its intended use. A true and accurate copy of Nihon Kohden's "Bedside Monitor Specification Comparison," which outlines the differences between the BSM-3500 and the BSM-6000, is attached hereto as **Exhibit C**.

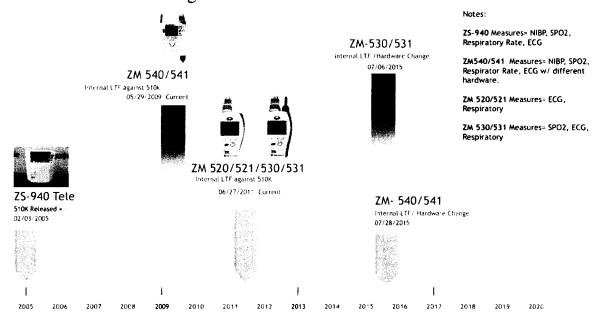
- 53. As a result, Nihon Kohden was required to file a premarket notification submission with the FDA seeking independent 510(k) clearance for the BSM-3500 device. Nihon Kohden was required to demonstrate how—despite these significant changes—the BSM-3500 was still substantially equivalent to the BSM-6000 series.
- 54. To date, Nihon Kohden has failed to file any such submission—and the BSM-3500 has no FDA approval or clearance. Instead (and as with the BSM-1700), Nihon Kohden simply filed an internal LTF against its original BSM-6000 series, and introduced the BSM-3500 into commerce without any premarket clearance/approval. In a letter to the FDA dated August 25, 2015, Nihon Kohden represented to the FDA that "[t]he BSM-3500 Series models are just additional models of the BSM-6000 Series." This statement is flat wrong.
- 55. Nihon Kohden continues to make additional changes to BSM-3500; and with each change, adds another internal LTF to the 6000 series. One LTF is specific to the marketing and release of the BSM-3500, describing it as an equivalent to the BSM-6000 series. Future LTFs for software changes and hardware configurations have all been filed against the original 510(k) for the BSM-6000 series (with some software/hardware changes not being LTF'd at all).
- 56. Like the BSM-1700, the BSM-3500 has been on the market for several years and is now regularly used by healthcare providers across the nation. The BSM-3500 is one of Nihon Kohden's top selling devices and costs approximately \$6,000.

C. Tele-Transmitter(s)

57. In 2005, Nihon Kohden's ZS-940 transmitter received 510(k) clearance. Since then, Nihon Kohden has released at least ten new devices, each containing substantial changes regarding their hardware, software, user interface,

and intended uses. Such devices included: (i) the ZM-540 and ZM-541 (released in 2009); (ii) the ZM-530, ZM 521, ZM-530, and ZM-531 (released in 2011), and ZM-530, ZM-531, ZM-540, and ZM-541 (released in 2015).

- 58. These new devices are completely different compared to the original ZS-940. As such, each of these new devices required their own separate 510(k) clearance. But instead, Nihon Kohden simply added an internal LTF against its original ZS-940 device (which received clearance back in 2005). None of the new devices were submitted or reviewed by the FDA, but were nevertheless introduced marketed, distributed and sold by Nihon Kohden.
 - 59. The following chart illustrates this timeline.



60. These tele-transmitter devices cost approximately \$3,000 per transmitter, depending on the model and feature set. However, telemetry transmitters also require a receiver device which cost another \$12,000 - \$14,000 per device. Telemetry transmitters are some of the most popular devices sold, exceeding the volume of bedside monitor sales. These devices make up a substantial portion of Nihon Kohden's annual revenue.

D. The Remote Network Station (RNS-9703)

- 61. In 2010, Nihon Kohden obtained 510(k) clearance for its CNS-6200 Central Nurse Station. The device was cleared for use to provide cardiac and vital signs monitoring for multiple patients within a medical facility. The CNS-6200 displays and records physiological data from individual bedside monitors and/or telemetry received transmitters and mimics an alarm when a measured parameter falls outside a preset limit.
- 62. In 2014, Nihon Kohden introduced the remote network station, RNS-9703, which provides for secondary monitoring of up to sixteen patients who are centrally monitored on a CNS. Compared to the CNS, the RNS has significant changes and modifications to its design, material, energy source, manufacturing process, and its intended use.
- 63. For example, the CNS serves as the primary monitoring station for all BSM-6000s/17000s/3000s and tele-transmitters, allowing hospitals' nurses to view and monitor patients remotely (typically from a nurse station), and stores patient data on a hard drive. In contrast, the RNS is an independent viewing station with different hardware and software and which requires an "RNS Server" on the network to enable the devices overall functionally. Unlike the CNS, no data is stored on the RNS, and such data is displayed in real-time.
- 64. Given these significant changes and modifications, Nihon Kohden was required to file a premarket notification submission with the FDA seeking independent 510(k) clearance for the RNS. Nihon Kohden was required to demonstrate how—despite these significant changes—the RNS was still substantially equivalent to the CNS. To date, Nihon Kohden has failed to file any such submission. Instead, Nihon Kohden introduced the RNS-9703 as an "accessory" to the CNS as a means to circumvent the 510(k) approval process. Rather than submit a 510(k) for the RNS, Nihon Kohden simply added an internal LTF to its CNS file, and introduced the BSM-1700 into commerce without any

premarket clearance/approval.

65. The RNS has now been on the market for eight years and costs approximately \$7,350. Approximately 200-250 RNS units are sold annually.

* * * * *

- 66. With respect to all of these devices, Nihon Kohden knew that the Monitoring Devices either did not have the same intended use as their predicates (including off-label uses), had different technological characteristics (including significant hardware and software alterations), and raised safety and efficacy issues. As a result, the Monitoring Devices all needed their own independent 510(k) clearance (if not a wholly new and separate FDA premarket approval). Nihon Kohden did neither, yet still introduced the Monitoring Devices into interstate commerce.
- 67. Nihon Kohden has received multiple complaints from consumers regarding these Monitoring Devices. For example, Nihon Kohden has received constant complaints of communication losses amongst devices, where patient data and information is not being reported from device to device. Nihon Kohden has also received complaints about devices failing due to software upgrades. This is because Nihon Kohden rushes its monitoring devices to market without first conducting adequate testing.
- 68. Because these devices are all adulterated/misbranded/off-label, Nihon Kohden never once submitted any of these complaints to the FDA. Had Nihon Kohden done so, it would have notified the FDA that it was marketing and distributing adulterated/misbranded/off-label devices. As a result, numerous consumer complaints go unreported each year.
- 69. In fact, Nihon Kohden has even recalled several Monitoring Devices in response to consumer complaints. For example, one significant recall in 2016 was against the RNS-9703 product—which never received 510(k) clearance, only an internal LTF. But once again, because these Monitoring Devices are all

adulterated/misbranded/off-label and not filed with the FDA, these recalls go unreported as well.

- 70. This type of fraud has been occurring at Nihon Kohden for many years and is pervasive across its entire business. Multiple employees, including Relators, have voiced concerns about the LTF process to Nihon Kohden's leadership. Mr. Finch has reported these specific issues to Nihon Kohden's Vice President of Human Resources, who wholly ignored this issue and declined to perform any investigation into the various adulterated/misbranded/off-label devices. In many research and development meetings, various product managers and senior engineers would also state that alterations of these devices require new 510(k) submissions with the FDA, rather than an internal LTF. All of these concerns have been ignored, and Nihon Kohden still continues its fraud to this day.
- 71. At all relevant times, Nihon Kohden knew that the Government routinely paid hospitals for their use of the Monitoring Devices. Thus, Nihon Kohden knew that the Government would receive numerous claims for reimbursement for their Monitoring Devices. Nihon Kohden also knew that the Government (including all federal and state funded healthcare programs) would not pay for the use of these Monitoring Devices. In fact, had the Government known that the Monitoring Devices were adulterated/misbranded/off-label and lacked FDA clearance, the Government would not have paid the reimbursement claims. Consequently, every claim presented to the Government for use of a Monitoring Device was a false claim, and each claim was knowingly caused by Nihon Kohden.
- 72. The damages incurred by the Government as a result of the foregoing fraud are substantial. This fraud impacts all Government agencies that made any payment for use of a Monitoring Device, including all reimbursement claims paid by federal and state healthcare programs, as well as all payments made pursuant to any federal defense contracts. Relators estimate that, since 2012, the Government has improperly paid tens of millions of dollars in false claims for the

adulterated/misbranded/off-label Monitoring Devices.

COUNT ONE

VIOLATION OF THE FALSE CLAIMS ACT

31 U.S.C. § 3729(a)(1)(A)

- 73. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 74. As set forth above, from at least 2012 through the present, Defendants presented false or fraudulent claims for payment, or knowingly caused false or fraudulent claims for payment to be presented, to officials of the United States Government in violation of 31 U.S.C. § 3729(a)(1)(A).
- 75. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the United States suffered actual damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWO

VIOLATION OF THE FALSE CLAIMS ACT

31 U.S.C. § 3729(a)(1)(B)

- 76. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 77. As set forth above, from at least 2012 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B). Defendants knowingly and falsely certified that its claims for reimbursement complied with all applicable laws and regulations.
- 78. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the United States suffered actual damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty for each violation.

2

4

56

7

8

10

11

12

13

14

1516

17

18

1920

21

2223

2425

26

2728

COUNT THREE

VIOLATION OF THE FALSE CLAIM ACT

31 U.S.C. 3729(a)(1)(C)

- 79. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as through fully set forth herein.
- 80. As set forth above, from at least 2012 through the present, Defendants knowingly conspired to commit a violation of the False Claims Act in violation of 31 U.S.C. §3729(a)(1)(C).
- 81. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the United States suffered actual damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FOUR

VIOLATION OF THE ALASKA MEDICAL ASSISTANCE FALSE CLAIMS AND REPORTING ACT

ALASKA STAT. § 09.58.010(a)(1)

- 82. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 83. This is a claim for penalties and treble damages under the Alaska Medical Assistance False Claims and Reporting Act.
- 84. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Alaska false or fraudulent claims for payment or approval in violation of Alaska Stat. § 09.58.010(a)(1).
- 85. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Alaska suffered actual damages and therefore is entitled to multiple damages under the Alaska Medical Assistance False Claims and Reporting Act, to be determined at trial, plus a civil penalty for each violation.

2

3

5

6

7 8

9 10

1112

13 14

16

15

1718

19

2021

2223

2425

2627

28

COUNT FIVE

VIOLATION OF THE ALASKA MEDICAL ASSISTANCE FALSE CLAIMS AND REPORTING ACT

ALASKA STAT. § 09.58.010(a)(2)

- 86. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 87. This is a claim for penalties and treble damages under Alaska Medical Assistance False Claims and Reporting Act.
- 88. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Alaska in violation of in violation of Alaska Stat. § 09.58.010(a)(2).
- 89. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Alaska suffered actual damages and therefore is entitled to multiple damages under the Alaska Medical Assistance False Claims and Reporting Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIX

VIOLATION OF THE ALASKA MEDICAL ASSISTANCE FALSE CLAIMS AND REPORTING ACT

ALASKA STAT. § 09.58.010(a)(3)

- 90. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 91. This is a claim for penalties and treble damages under the Alaska Medical Assistance False Claims and Reporting Act.
- 92. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Alaska Medical Assistance False Claims and Reporting Act in violation of Alaska Stat. § 09.58.010(a)(3).

93. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Alaska suffered actual damages and therefore is entitled to multiple damages under the Alaska Medical Assistance False Claims and Reporting Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVEN

VIOLATION OF THE CALIFORNIA FALSE CLAIMS ACT

CAL. GOV'T CODE § 12651(A)(1)

- 94. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 95. This is a claim for penalties and treble damages under the California False Claims Act.
- 96. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of California false or fraudulent claims for payment or approval in violation of Cal. Gov't Code §12651(A)(1).
- 97. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of California suffered actual damages and therefore is entitled to multiple damages under the California False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHT

VIOLATION OF THE CALIFORNIA FALSE CLAIMS ACT

CAL. GOV'T CODE § 12651(A)(2)

- 98. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 99. This is a claim for penalties and treble damages under the California False Claims Act.
- 100. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements

material to a false or fraudulent claim submitted to the State of California in violation of in violation of Cal. Gov't Code §12651(A)(2).

101. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of California suffered actual damages and therefore is entitled to multiple damages under the California False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT NINE

VIOLATION OF THE CALIFORNIA FALSE CLAIMS ACT

CAL. GOV'T CODE § 12651(A)(3)

- 102. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 103. This is a claim for penalties and treble damages under the California False Claims Act.
- 104. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the California False Claims Act in violation of Cal. Gov't Code §12651(A)(3).
- 105. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of California suffered actual damages and therefore is entitled to multiple damages under the California False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TEN

VIOLATION OF THE COLORADO MEDICAID FALSE CLAIMS ACT

COLO. REV. STAT. §25.5-4-305(1)(a)

- 106. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 107. This is a claim for penalties and treble damages under the Colorado Medicaid False Claims Act.
 - 108. As set forth above, from at least 2011 through the present, Defendants

knowingly presented or caused to be presented to the State of Colorado false or fraudulent claims for payment or approval in violation of Colo. Rev. Stat. §25.5-4-305(1)(a).

109. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Colorado suffered actual damages and therefore is entitled to multiple damages under the Colorado Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT ELEVEN

VIOLATION OF THE COLORADO MEDICAID FALSE CLAIMS ACT COLO. REV. STAT. §25.5-4-305(1)(b)

- 110. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 111. This is a claim for penalties and treble damages under the Colorado Medicaid False Claims Act.
- 112. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Colorado in violation of Colo. Rev. Stat. §25.5-4-305(1)(b).
- 113. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Colorado suffered actual damages and therefore is entitled to multiple damages under the Colorado Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWELVE

VIOLATION OF THE COLORADO MEDICAID FALSE CLAIMS ACT COLO. REV. STAT. §25.5-4-305(1)(g)

- 114. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
 - 115. This is a claim for penalties and treble damages under the Colorado

Medicaid False Claims Act.

- 116. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Colorado Medicaid False Claims Act in violation of Colo. Rev. Stat. §25.5-4-305(1)(g).
- 117. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Colorado suffered actual damages and therefore is entitled to multiple damages under the Colorado Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTEEN

VIOLATION OF THE CONNECTICUT FALSE CLAIMS

CONN GEN. STAT. §4-275(1)

- 118. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 119. This is a claim for penalties and treble damages under the Connecticut False Claims Act.
- 120. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Connecticut false or fraudulent claims for payment or approval in violation of Conn. Gen. Stat. §4-275(1).
- 121. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Connecticut suffered actual damages and therefore is entitled to multiple damages under the Connecticut False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FOURTEEN

VIOLATION OF THE CONNECTICUT FALSE CLAIMS ACT FOR MEDICAL ASSISTANCE PROGRAMS

CONN. GEN. STAT. §4-275(2)

122. Relator incorporates by reference the allegations set forth in the

foregoing paragraphs as though fully set forth herein.

- 123. This is a claim for penalties and treble damages under the Connecticut False Claims Act.
- 124. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Connecticut in violation of Conn. Gen. Stat. §4-275(2).
- 125. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Connecticut suffered actual damages and therefore is entitled to multiple damages under the Connecticut False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTEEN

VIOLATION OF THE CONNECTICUT FALSE CLAIMS ACT FOR MEDICAL ASSISTANCE PROGRAMS

CONN. GEN. STAT. §4-275(3)

- 126. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 127. This is a claim for penalties and treble damages under the Connecticut False Claims Act for Medical Assistance Programs.
- 128. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Connecticut False Claims Act in violation of Conn. Gen. Stat. §4-275(3).
- 129. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Connecticut suffered actual damages and therefore is entitled to multiple damages under the Connecticut False Claims Act, to be determined at trial, plus a civil penalty for each violation.

1 **COUNT SIXTEEN** VIOLATION OF THE DELAWARE FALSE CLAIMS 2 AND REPORTING ACT 3 **DEL. CODE ANN. § 1201(a)(1)** 4 130. Relator incorporates by reference the allegations set forth in the 5 6 foregoing paragraphs as though fully set forth herein. 131. This is a claim for penalties and treble damages under the Delaware 7 8 False Claims and Reporting Act. 9 132. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Delaware false or 10 11 fraudulent claims for payment or approval in violation of Del. Code Ann. 12 §1201(a)(1) 133. By virtue of the false or fraudulent claims submitted or caused to be 13 submitted by Defendants, the State of Delaware suffered actual damages and 14 15 therefore is entitled to multiple damages under the Delaware False Claims and Reporting Act, to be determined at trial, plus a civil penalty for each violation. 16 **COUNT SEVENTEEN** 17 VIOLATION OF THE DELAWARE FALSE CLAIMS 18 19 AND REPORTING ACT 20 **DEL. CODE ANN. §1201(a)(2)** 134. Relator incorporates by reference the allegations set forth in the 21 22 foregoing paragraphs as though fully set forth herein. 135. This is a claim for penalties and treble damages under the Delaware 23 24 False Claims and Reporting Act. 136. As set forth above, from at least 2011 through the present, Defendants 25 knowingly made, used, or caused to be made or used false records or statements 26 material to a false or fraudulent claim submitted to the State of Delaware in violation 27 of Del. Code Ann. §1201(a)(2). 28

137. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Delaware suffered actual damages and therefore is entitled to multiple damages under the Delaware False Claims and Reporting Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTEEN

VIOLATION OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT

DEL. CODE ANN. §1201(a)(3)

- 138. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 139. This is a claim for penalties and treble damages under the Delaware False Claims and Reporting Act.
- 140. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Delaware False Claims and Reporting Act in violation of Del. Code Ann. §1201(a)(3).
- 141. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Delaware suffered actual damages and therefore is entitled to multiple damages under the Delaware False Claims and Reporting Act, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETEEN

VIOLATION OF THE DISTRICT OF COLUMBIA FALSE CLAIMS ACT D.C. CODE §2-381.02(a)(1)

- 142. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 143. This is a claim for penalties and treble damages under the District of Columbia False Claims Act.
- 144. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the District of Columbia false or

fraudulent claims for payment or approval in violation of D.C. Code. §2-381.02(a)(1).

145. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the District of Columbia suffered actual damages and therefore is entitled to multiple damages under the District of Columbia False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWENTY

VIOLATION OF THE DISTRICT OF COLUMBIA FALSE CLAIMS ACT D.C. CODE §2-381.02(a)(2)

- 146. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 147. This is a claim for penalties and treble damages under the District of Columbia False Claims Act.
- 148. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the District of Columbia in violation of D.C. Code §2-381.02(a)(2).
- 149. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the District of Columbia suffered actual damages and therefore is entitled to multiple damages under the District of Columbia False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWENTY-ONE

VIOLATION OF THE DISTRICT OF COLUMBIA FALSE CLAIMS ACT D.C. CODE §2-381.02(a)(3)

- 150. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 151. This is a claim for penalties and treble damages under the District of Columbia False Claims Act.

- 152. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the District of Columbia False Claims Act in violation of D.C. Code §2-381.02(a)(3).
- 153. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the District of Columbia suffered actual damages and therefore is entitled to multiple damages under the District of Columbia False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWENTY-TWO

VIOLATION OF THE FLORIDA FALSE CLAIMS ACT

FLA. STAT. §68.082(2)(a)

- 154. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 155. This is a claim for penalties and treble damages under the Florida False Claims Act.
- 156. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Florida false or fraudulent claims for payment or approval in violation of Fla. Stat. §68.082(2)(a).
- 157. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Florida suffered actual damages and therefore is entitled to multiple damages under the Florida False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWENTY-THREE

VIOLATION OF THE FLORIDA FALSE CLAIMS ACT

FLA. STAT. §68.082(2)(b)

- 158. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 159. This is a claim for penalties and treble damages under the Florida False Claims Act.

- 160. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Florida in violation of Fla. Stat. §68.082(2)(b).
- 161. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Florida suffered actual damages and therefore is entitled to multiple damages under the Florida False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWENTY-FOUR

VIOLATION OF THE FLORIDA FALSE CLAIMS ACT

FLA. STAT. §68.082(2)(c)

- 162. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 163. This is a claim for penalties and treble damages under the Florida False Claims Act.
- 164. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Florida False Claims Act in violation of Fla. Stat. §68.082(2)(c).
- 165. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Florida suffered actual damages and therefore is entitled to multiple damages under the Florida False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWENTY-FIVE

VIOLATION OF THE GEORGIA

STATE FALSE MEDICAID CLAIMS ACT

GA. CODE ANN. §49-4-168.1(a)(1)

166. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

- 167. This is a claim for penalties and treble damages under the Georgia State False Medicaid Claims Act.
- 168. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Georgia false or fraudulent claims for payment or approval in violation of Ga. Code Ann. §49-4-168.1(a)(1).
- 169. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Georgia suffered actual damages and therefore is entitled to multiple damages under the Georgia State False Medicaid Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWENTY-SIX

VIOLATION OF THE GEORGIA

STATE FALSE MEDICAID CLAIMS ACT

GA. CODE ANN. §49-4-168.1(a)(2)

- 170. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 171. This is a claim for penalties and treble damages under the Georgia State False Medicaid Claims Act.
- 172. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Georgia in violation of Ga. Code Ann. §49-4-168.1(a)(2).
- 173. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Georgia suffered actual damages and therefore is entitled to multiple damages under the Georgia State False Medicaid Claims Act, to be determined at trial, plus a civil penalty for each violation.

1 COUNT TWENTY-SEVEN 2 VIOLATION OF THE GEORGIA STATE FALSE MEDICAID CLAIMS ACT 3 4 GA. CODE ANN. §49-4-168.1(a)(3) 174. Relator incorporates by reference the allegations set forth in the 5 foregoing paragraphs as though fully set forth herein. 6 175. This is a claim for penalties and treble damages under the Georgia State 7 8 False Medicaid Claims Act. 9 176. As set forth above, from at least 2011 through the present, Defendants 10 knowingly conspired together to commit violations of the Georgia State False Medicaid Claims Act in violation of Ga. Code Ann. §49-4-168.1(a)(3). 11 12 177. By virtue of the false or fraudulent claims submitted or caused to be 13 submitted by Defendants, the State of Georgia suffered actual damages and therefore is entitled to multiple damages under the Georgia State False Medicaid Claims Act, 14 to be determined at trial, plus a civil penalty for each violation. 15 16 **COUNT TWENTY-EIGHT** 17 VIOLATION OF THE HAWAII FALSE CLAIMS ACT 18 HAW. REV. STAT. §661-21(a)(1) 178. Relator incorporates by reference the allegations set forth in the 19 20 foregoing paragraphs as though fully set forth herein. 21 179. This is a claim for penalties and treble damages under the Hawaii False Claims Act. 22 180. As set forth above, from at least 2011 through the present, Defendants 23 24 knowingly presented or caused to be presented to the State of Hawaii false or 25 fraudulent claims for payment or approval in violation of Haw. Rev. Stat. §661.21(a)(1). 26 27 181. By virtue of the false or fraudulent claims submitted or caused to be

submitted by Defendants, the State of Hawaii suffered actual damages and therefore

is entitled to multiple damages under the Hawaii False Claims Act, to be determined 1 at trial, plus a civil penalty for each violation. 2 **COUNT TWENTY-NINE** 3 VIOLATION OF THE HAWAII FALSE CLAIMS ACT 4 HAW. REV. STAT. §661-21(a)(2) 5 182. Relator incorporates by reference the allegations set forth in the 6 foregoing paragraphs as though fully set forth herein. 7 183. This is a claim for penalties and treble damages under the Hawaii False 8 9 Claims Act. 10 184. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements 11 material to a false or fraudulent claim submitted to the State of Hawaii in violation 12 13 of Haw. Rev. Stat. §661-21(a)(2). 185. By virtue of the false or fraudulent claims submitted or caused to be 14 submitted by Defendants, the State of Hawaii suffered actual damages and therefore 15 is entitled to multiple damages under the Hawaii False Claims Act, to be determined 16 at trial, plus a civil penalty for each violation. 17 18 **COUNT THIRTY** VIOLATION OF THE HAWAII FALSE CLAIMS ACT 19 HAW. REV. STAT. §661-21(a)(8) 20 186. Relator incorporates by reference the allegations set forth in the 21 foregoing paragraphs as though fully set forth herein. 22 23 187. This is a claim for penalties and treble damages under the Hawaii False Claims Act. 24 188. As set forth above, from at least 2011 through the present, Defendants 25 knowingly conspired together to commit violations of the Hawaii False Claims Act 26 27 in violation of Haw. Rev. Stat. §661-21(a)(8). 189. By virtue of the false or fraudulent claims submitted or caused to be 28

submitted by Defendants, the State of Hawaii suffered actual damages and therefore is entitled to multiple damages under the Hawaii False Claims Act, to be determined at trial, plus a civil penalty for each violation

COUNT THIRTY-ONE

VIOLATION OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

740 ILL. COMP. STAT. §175/3(a)(1)(A)

- 190. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 191. This is a claim for penalties and treble damages under the Illinois Whistleblower and Protection Act.
- 192. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Illinois false or fraudulent claims for payment or approval in violation of 740 Ill. Comp. Stat. §175/3(a)(1)(A).
- 193. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Illinois suffered actual damages and therefore is entitled to multiple damages under the Illinois Whistleblower and Protection Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTY-TWO

VIOLATION OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

740 ILL. COMP. STAT. §175/3(a)(1)(B)

- 194. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 195. This is a claim for penalties and treble damages under the Illinois Whistleblower and Protection Act.
 - 196. As set forth above, from at least 2011 through the present, Defendants

knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Illinois in violation of 740 Ill. Comp. Stat. §175/3(a)(1)(B).

197. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Illinois suffered actual damages and therefore is entitled to multiple damages under the Illinois Whistleblower and Protection Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTY-THREE

VIOLATION OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

740 ILL. COMP. STAT. §175/3(a)(1)(C)

- 198. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 199. This is a claim for penalties and treble damages under the Illinois Whistleblower and Protection Act.
- 200. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Illinois Whistleblower and Protection Act in violation of 740 Ill. Comp. Stat. §175/3(a)(1)(C).
- 201. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Illinois suffered actual damages and therefore is entitled to multiple damages under the Illinois Whistleblower and Protection Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTY-FOUR

VIOLATION OF THE INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

IND. CODE §5-11-5.5-2(b)(1) & (8)

202. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

- 203. This is a claim for penalties and treble damages under the Indiana False Claims and Whistleblower Protection Act.
- 204. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Indiana false or fraudulent claims for payment or approval in violation of Ind. Code. §5-11-5.5-2(b)(1) & (8).
- 205. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Indiana suffered actual damages and therefore is entitled to multiple damages under the Indiana False Claims and Whistleblower Protection Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTY-FIVE

VIOLATION OF THE INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

IND. CODE §5-11-5.5-2(b)(2) & (8)

- 206. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 207. This is a claim for penalties and treble damages under the Indiana False Claims and Whistleblower Protection Act.
- 208. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Indiana in violation of Ind. Code §5-11-5.5-2(b)(2) & (8).
- 209. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Indiana suffered actual damages and therefore is entitled to multiple damages under the Indiana False Claims and Whistleblower Protection Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTY-SIX

VIOLATION OF THE INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

IND. CODE §5-11-5.5-2(b)(7)

- 210. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 211. This is a claim for penalties and treble damages under the Indiana False Claims and Whistleblower Protection Act.
- 212. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Indiana False Claims and Whistleblower Protection Act in violation of Ind. Code §5-11-5.5-2(b)(7).
- 213. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Indiana suffered actual damages and therefore is entitled to multiple damages under the Indiana False Claims and Whistleblower Protection Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTY-SEVEN

VIOLATION OF THE IOWA FALSE CLAIMS ACT

IOWA CODE §685.2(1)(a)

- 214. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 215. This is a claim for penalties and treble damages under the Iowa False Claims Act.
- 216. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Iowa false or fraudulent claims for payment or approval in violation of Iowa Code §685.2(1)(a).
- 217. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Iowa suffered actual damages and therefore is entitled to multiple damages under the Iowa False Claims Act, to be determined at

trial, plus a civil penalty for each violation.

COUNT THIRTY-EIGHT

VIOLATION OF THE IOWA FALSE CLAIMS ACT

IOWA CODE §685.2(1)(b)

- 218. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 219. This is a claim for penalties and treble damages under the Iowa False Claims Act.
- 220. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Iowa in violation of Iowa Code §685.2(1)(b).
- 221. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Iowa suffered actual damages and therefore is entitled to multiple damages under the Iowa False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTY-NINE

VIOLATION OF THE IOWA FALSE CLAIMS ACT

IOWA CODE §685.2(1)(c)

- 222. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 223. This is a claim for penalties and treble damages under the Iowa False Claims Act.
- 224. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Iowa False Claims Act in violation of Iowa Code §685.2(1)(c).
- 225. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Iowa suffered actual damages and therefore is

1 entitled to multiple damages under the Iowa False Claims Act, to be determined at trial, plus a civil penalty for each violation. 2 **COUNT FORTY** 3 VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE 4 PROGRAMS INTEGRITY LAW 5 La. STAT. ANN. §46:438.3(A) 6 226. Relator incorporates by reference the allegations set forth in the 7 8 foregoing paragraphs as though fully set forth herein. 9 227. This is a claim for penalties and treble damages under the Louisiana Medical Assistance Programs Integrity Law. 10 228. As set forth above, from at least 2011 through the present, Defendants 11 knowingly presented or caused to be presented to the State of Louisiana false or 12 fraudulent claims for payment or approval in violation of La. Stat. Ann. 13 §46:438.3(A). 14 229. By virtue of the false or fraudulent claims submitted or caused to be 15 submitted by Defendants, the State of Louisiana suffered actual damages and 16 therefore is entitled to multiple damages under the Louisiana Medical Assistance 17 18 Programs Integrity Law, to be determined at trial, plus a civil penalty for each 19 violation. **COUNT FORTY-ONE** 20 VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE 21 PROGRAMS INTEGRITY LAW 22 La. STAT. ANN. §46:438.3(B) 23 230. Relator incorporates by reference the allegations set forth in the 24 foregoing paragraphs as though fully set forth herein. 25 231. This is a claim for penalties and treble damages under the Louisiana 26 Medical Assistance Programs Integrity Law. 27

28

232. As set forth above, from at least 2011 through the present, Defendants

knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Louisiana in violation of La. Stat. Ann. §46:438.3(B).

233. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Louisiana suffered actual damages and therefore is entitled to multiple damages under the Louisiana Medical Assistance Programs Integrity Law, to be determined at trial, plus a civil penalty for each violation.

COUNT FORTY-TWO

VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

La. Stat. Ann. §46:438.3(D)

- 234. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 235. This is a claim for penalties and treble damages under the Louisiana Medical Assistance Programs Integrity Law.
- 236. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Louisiana Medical Assistance Programs Integrity Law in violation of La. Stat. Ann. §46:438.3(D).
- 237. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Louisiana suffered actual damages and therefore is entitled to multiple damages under the Louisiana Medical Assistance Programs Integrity Law, to be determined at trial, plus a civil penalty for each violation.

COUNT FORTY-THREE

VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

La. STAT. ANN. §46:438.2(A)

- 238. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 239. This is a claim for penalties and treble damages under the Louisiana Medical Assistance Programs Integrity Law.
- 240. As set forth above, from at least 2011 through the present, Defendants knowingly solicited, received, offered, and paid remuneration in return for purchasing and ordering goods for which payment may be made under Louisiana's Medical Assistance Program in violation of La. Stat. § 46:438.2(A).
- 241. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Louisiana suffered actual damages and therefore is entitled to multiple damages under the Louisiana Medical Assistance Programs Integrity Law, to be determined at trial, plus a civil penalty for each violation.

COUNT FORTY-FOUR

VIOLATION OF THE MARYLAND FALSE CLAIMS ACT

MD. CODE ANN., Health – Gen., §2-602(a)(1)

- 242. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 243. This is a claim for penalties and treble damages under the Maryland False Claims Act.
- 244. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Maryland false or fraudulent claims for payment or approval in violation of MD. Code Ann., Health Gen., §2-702(a)(1).

245. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Maryland suffered actual damages and therefore is entitled to multiple damages under the Maryland False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FORTY-FIVE

VIOLATION OF THE MARYLAND FALSE CLAIMS ACT

MD. CODE ANN., Health – Gen., $\S 2-602(a)(2)$

- 246. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 247. This is a claim for penalties and treble damages under the Maryland False Claims Act.
- 248. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Maryland in violation of MD. Code Ann., Health Gen., §2-602(a)(2).
- 249. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Maryland suffered actual damages and therefore is entitled to multiple damages under the Maryland False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FORTY-SIX

VIOLATION OF THE MARYLAND FALSE CLAIMS ACT

MD. CODE ANN., Health – Gen., §2-602(a)(3)

- 250. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 251. This is a claim for penalties and treble damages under the Maryland False Claims Act.
- 252. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Maryland False Claims

Act in violation of MD Code Ann., Health – Gen., §2-601(a)(3).

253. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Maryland suffered actual damages and therefore is entitled to multiple damages under the Maryland False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FORTY-SEVEN

VIOLATION OF THE MASSACHUSETTS FALSE CLAIMS ACT

MASS. GEN. LAWS, ch. 12, § 5B(a)(1)

- 254. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 255. This is a claim for penalties and treble damages under the Massachusetts False Claims Act.
- 256. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the Commonwealth of Massachusetts false or fraudulent claims for payment or approval in violation of Mass. Gen. Laws, ch. 12, §5B(a)(1).
- 257. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the Commonwealth of Maryland suffered actual damages and therefore is entitled to multiple damages under the Massachusetts False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FORTY-EIGHT

VIOLATION OF THE MASSACHUSETTS FALSE CLAIMS ACT Mass. Gen. Laws, ch. 12, § 5B(a)(2)

- 258. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 259. This is a claim for penalties and treble damages under the Massachusetts False Claims Act.
 - 260. As set forth above, from at least 2011 through the present, Defendants

knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the Commonwealth of Massachusetts in violation of Mass. Gen. Laws, ch. 12, §5B(a)(2).

261. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the Commonwealth of Massachusetts suffered actual damages and therefore is entitled to multiple damages under the Massachusetts False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FORTY-NINE

VIOLATION OF THE MASSACHUSETTS FALSE CLAIMS ACT Mass. Gen. Laws, ch. 12, § 5B(a)(3)

- 262. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 263. This is a claim for penalties and treble damages under the Massachusetts False Claims Act.
- 264. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Massachusetts False Claims Act in violation of Mass. Gen. Laws, ch. 12, §5B(a)(3).
- 265. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the Commonwealth suffered actual damages and therefore is entitled to multiple damages under the Massachusetts False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTY

VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT MICH. COMP. LAWS § 400.607(1)

- 266. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 267. This is a claim for penalties and treble damages under the Michigan Medicaid False Claims Act.

- 268. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Michigan false or fraudulent claims for payment or approval in violation of Mich. Comp. Laws §400.607(1).
- 269. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Michigan suffered actual damages and therefore is entitled to multiple damages under the Michigan Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTY-ONE

VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT MICH. COMP. LAWS § 400.607(2)

- 270. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 271. This is a claim for penalties and treble damages under the Michigan Medicaid False Claims Act.
- 272. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Michigan in violation of Mich. Comp. Laws §400.607(2).
- 273. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Michigan suffered actual damages and therefore is entitled to multiple damages under the Michigan Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTY-TWO

VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT MICH. COMP. LAWS § 400.606(1)

274. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

- 275. This is a claim for penalties and treble damages under the Michigan Medicaid False Claims Act.
- 276. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Michigan Medicaid False Claims Act in violation of Mich. Comp. Laws §400.606(1).
- 277. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Michigan suffered actual damages and therefore is entitled to multiple damages under the Michigan Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTY-THREE

VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT MICH. COMP. LAWS § 400.604

- 278. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 279. This is a claim for penalties and treble damages under the Michigan Medicaid False Claims Act.
- 280. As set forth above, from at least 2011 through the present, Defendants knowingly solicited, offered, and/or received kickbacks or bribes in connection with the furnishing of goods for which payment may be made by the State of Michigan in violation of Mich. Comp. Laws §400.604.
- 281. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Michigan suffered actual damages and therefore is entitled to multiple damages under the Michigan Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTY-FOUR

VIOLATION OF THE MINNESOTA FALSE CLAIMS ACT

MINN. STAT. §15C.02(a)(1)

282. Relator incorporates by reference the allegations set forth in the

foregoing paragraphs as though fully set forth herein.

- 283. This is a claim for penalties and treble damages under the Minnesota False Claims Act.
- 284. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Minnesota false or fraudulent claims for payment or approval in violation of Minn. Stat. §15C.02(a)(1).
- 285. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Minnesota suffered actual damages and therefore is entitled to multiple damages under the Minnesota False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTY-FIVE

VIOLATION OF THE MINNESOTA FALSE CLAIMS ACT MINN. STAT. §15C.02(a)(2)

- 286. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 287. This is a claim for penalties and treble damages under the Minnesota False Claims Act.
- 288. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Minnesota in violation of Minn. Stat. §15C.02(a)(2).
- 289. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Minnesota suffered actual damages and therefore is entitled to multiple damages under the Minnesota False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTY-SIX 1 VIOLATION OF THE MINNESOTA FALSE CLAIMS ACT 2 3 MINN. STAT. $\S15C.02(a)(3)$ 290. Relator incorporates by reference the allegations set forth in the 4 foregoing paragraphs as though fully set forth herein. 5 291. This is a claim for penalties and treble damages under the Minnesota 6 7 False Claims Act. 292. As set forth above, from at least 2011 through the present, Defendants 8 knowingly conspired together to commit violations of the Minnesota False Claims 9 Act in violation of Minn. Stat. §15C.02(a)(3). 10 293. By virtue of the false or fraudulent claims submitted or caused to be 11 submitted by Defendants, the State of Minnesota suffered actual damages and 12 therefore is entitled to multiple damages under the Minnesota False Claims Act, to 13 14 be determined at trial, plus a civil penalty for each violation. **COUNT FIFTY-SEVEN** 15 VIOLATION OF THE MONTANA FALSE CLAIMS ACT 16 MONT. CODE ANN. §17-8-403(1)(a) 17 294. Relator incorporates by reference the allegations set forth in the 18 19 foregoing paragraphs as though fully set forth herein. 295. This is a claim for penalties and treble damages under the Montana 20 False Claims Act. 21 296. As set forth above, from at least 2011 through the present, Defendants 22 23 knowingly presented or caused to be presented to the State of Montana false or fraudulent claims for payment or approval in violation of Mont. Code Ann. §17-8-24 403(1)(a). 25 297. By virtue of the false or fraudulent claims submitted or caused to be 26 submitted by Defendants, the State of Montana suffered actual damages and 27

therefore is entitled to multiple damages under the Montana False Claims Act, to be

28

1 determined at trial, plus a civil penalty for each violation. **COUNT FIFTY-EIGHT** 2 VIOLATION OF THE MONTANA FALSE CLAIMS ACT 3 MONT. CODE ANN. §17-8-403(1)(b) 4 298. Relator incorporates by reference the allegations set forth in the 5 foregoing paragraphs as though fully set forth herein. 6 7 299. This is a claim for penalties and treble damages under the Montana 8 False Claims Act. 300. As set forth above, from at least 2011 through the present, Defendants 9 knowingly made, used, or caused to be made or used false records or statements 10 material to a false or fraudulent claim submitted to the State of Montana in violation 11 of Mont. Code. Ann. §17-8-403(1)(b). 12 301. By virtue of the false or fraudulent claims submitted or caused to be 13 submitted by Defendants, the State of Montana suffered actual damages and 14 therefore is entitled to multiple damages under the Montana False Claims Act, to be 15 determined at trial, plus a civil penalty for each violation. 16 17 **COUNT FIFTY-NINE** VIOLATION OF THE MONTANA FALSE CLAIMS ACT 18 MONT. CODE ANN. §17-8-403(1)(c) 19 302. Relator incorporates by reference the allegations set forth in the 20 foregoing paragraphs as though fully set forth herein. 21 303. This is a claim for penalties and treble damages under the Montana 22 23 False Claims Act. 304. As set forth above, from at least 2011 through the present, Defendants 24 knowingly conspired together to commit violations of the Montana False Claims Act 25 in violation of Mont. Code Ann. §17-8-403(1)(c). 26 305. By virtue of the false or fraudulent claims submitted or caused to be 27

submitted by Defendants, the State of Montana suffered actual damages and

28

therefore is entitled to multiple damages under the Montana False Claims Act, to be 1 2 determined at trial, plus a civil penalty for each violation. **COUNT SIXTY** 3 VIOLATION OF THE NEVADA FALSE CLAIMS ACT 4 NEV. REV. STAT. §357.040(1)(a) 5 306. Relator incorporates by reference the allegations set forth in the 6 foregoing paragraphs as though fully set forth herein. 7 307. This is a claim for penalties and treble damages under the Nevada False 8 9 Claims Act. 308. As set forth above, from at least 2011 through the present, Defendants 10 knowingly presented or caused to be presented to the State of Nevada false or 11 fraudulent claims for payment or approval in violation of Nev. Rev. Stat. 12 §357.040(1)(a). 13 309. By virtue of the false or fraudulent claims submitted or caused to be 14 submitted by Defendants, the State of Nevada suffered actual damages and therefore 15 is entitled to multiple damages under the Nevada False Claims Act, to be determined 16 at trial, plus a civil penalty for each violation. 17 18 **COUNT SIXTY-ONE** VIOLATION OF THE NEVADA FALSE CLAIMS ACT 19 NEV. REV. STAT. §357.040(1)(b) 20 310. Relator incorporates by reference the allegations set forth in the 21 foregoing paragraphs as though fully set forth herein. 22 311. This is a claim for penalties and treble damages under the Nevada False 23 24 Claims Act. 312. As set forth above, from at least 2011 through the present, Defendants 25 knowingly made, used, or caused to be made or used false records or statements 26 material to a false or fraudulent claim submitted to the State of Nevada in violation 27 28 of Nev. Rev. Stat. §357.040(1)(b).

313. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Nevada suffered actual damages and therefore is entitled to multiple damages under the Nevada False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY-TWO

VIOLATION OF THE NEVADA FALSE CLAIMS ACT

NEV. REV. STAT. §357.040(1)(i)

- 314. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 315. This is a claim for penalties and treble damages under the Nevada False Claims Act.
- 316. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Nevada False Claims Act in violation of Nev. Rev. Stat. §357.040(1)(i).
- 317. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Nevada suffered actual damages and therefore is entitled to multiple damages under the Nevada False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY-THREE

VIOLATION OF THE NEW HAMPSHIRE FALSE CLAIMS ACT N.H. REV. STAT. ANN. §167:61-b(I)(a)

- 318. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 319. This is a claim for penalties and treble damages under the New Hampshire False Claims Act.
- 320. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of New Hampshire false or fraudulent claims for payment or approval in violation of N.H. Rev. Stat. Ann.

2

4

3

56

7

8

9 10

1112

1314

1516

17

18 19

20

2122

23

2425

2627

28

 $\S167:61-b(I)(a)$.

321. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Hampshire suffered actual damages and therefore is entitled to multiple damages under the New Hampshire False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY-FOUR

VIOLATION OF THE NEW HAMPSHIRE FALSE CLAIMS ACT N.H. REV. STAT. ANN. §167:61-b(I)(b)

- 322. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 323. This is a claim for penalties and treble damages under the New Hampshire False Claims Act.
- 324. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of New Hampshire in violation of N.H. Rev. Stat. Ann. §167:61-b(I)(b).
- 325. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Hampshire suffered actual damages and therefore is entitled to multiple damages under the New Hampshire False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY-FIVE

VIOLATION OF THE NEW HAMPSHIRE FALSE CLAIMS ACT N.H. Rev. Stat. Ann. §167:61-b(I)(c)

- 326. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 327. This is a claim for penalties and treble damages under the New Hampshire False Claims Act.
 - 328. As set forth above, from at least 2011 through the present, Defendants

knowingly conspired together to commit violations of the New Hampshire False Claims Act in violation of N.H. Rev. Stat. Ann. §167:61-b(I)(c).

329. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Hampshire suffered actual damages and therefore is entitled to multiple damages under the New Hampshire False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY-SIX

VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT

N.J. STAT. ANN. §2A:32C-3(a)

- 330. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 331. This is a claim for penalties and treble damages under the New Jersey False Claims Act.
- 332. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of New Jersey false or fraudulent claims for payment or approval in violation of N.J. Stat. Ann. §2A:32C-3(a).
- 333. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Jersey suffered actual damages and therefore is entitled to multiple damages under the New Jersey False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY-SEVEN

VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT

N.J. STAT. ANN. §2A:32C-3(b)

- 334. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 335. This is a claim for penalties and treble damages under the New Jersey False Claims Act.

- 336. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of New Jersey in violation of N.J. Stat. Ann. §2A:32C-3(b).
- 337. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Jersey suffered actual damages and therefore is entitled to multiple damages under the New Jersey False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY-EIGHT

VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT

N.J. STAT. ANN. §2A:32C-3(c)

- 338. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 339. This is a claim for penalties and treble damages under the New Jersey False Claims Act.
- 340. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the New Jersey False Claims Act in violation of N.J. Stat. Ann. §2A:32C-3(c).
- 341. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Jersey suffered actual damages and therefore is entitled to multiple damages under the New Jersey False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY-NINE

VIOLATION OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT N.M. STAT. ANN. §27-14-4(A)

- 342. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
 - 343. This is a claim for penalties and treble damages under the New Mexico

Medicaid False Claims Act.

- 344. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of New Mexico false or fraudulent claims for payment or approval in violation of N.M. Stat. Ann. §27-14-4(A).
- 345. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Mexico suffered actual damages and therefore is entitled to multiple damages under the New Mexico Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTY

VIOLATION OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT N.M. STAT. ANN. §27-14-4(C)

- 346. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 347. This is a claim for penalties and treble damages under the New Mexico Medicaid False Claims Act.
- 348. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of New Mexico in violation of N.M. Stat. Ann. §27-14-4(C).
- 349. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Mexico suffered actual damages and therefore is entitled to multiple damages under the New Mexico Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTY-ONE

VIOLATION OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT N.M. STAT. ANN. §27-14-4(D)

350. Relator incorporates by reference the allegations set forth in the

foregoing paragraphs as though fully set forth herein.

- 351. This is a claim for penalties and treble damages under the New Mexico Medicaid False Claims Act.
- 352. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the New Mexico Medicaid False Claims Act in violation of N.M. Stat. Ann. §27-14-4(D).
- 353. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Mexico suffered actual damages and therefore is entitled to multiple damages under the New Mexico Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTY-TWO

VIOLATION OF THE NEW YORK FALSE CLAIMS ACT N.Y. STATE FIN. LAW §189(1)(a)

- 354. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 355. This is a claim for penalties and treble damages under the New York False Claims Act.
- 356. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of New York false or fraudulent claims for payment or approval in violation of N.Y. State Fin. Law §189(1)(a).
- 357. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New York suffered actual damages and therefore is entitled to multiple damages under the New York False Claims Act, to be determined at trial, plus a civil penalty for each violation.

3

45

67

8 9

1011

12

13 14

15

16

1718

19

2021

23

22

2425

2627

2728

COUNT SEVENTY-THREE

VIOLATION OF THE NEW YORK FALSE CLAIMS ACT

N.Y. STATE FIN. LAW §189(1)(b)

- 358. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 359. This is a claim for penalties and treble damages under the New York False Claims Act.
- 360. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of New York in violation of N.Y. State Fin. Law §189(1)(b).
- 361. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New York suffered actual damages and therefore is entitled to multiple damages under the New York False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTY-FOUR

VIOLATION OF THE NEW YORK FALSE CLAIMS ACT

N.Y. STATE FIN. LAW §189(1)(c)

- 362. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 363. This is a claim for penalties and treble damages under the New York False Claims Act.
- 364. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the New York False Claims Act in violation of N.Y. State Fin. Law §189(1)(c).
- 365. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New York suffered actual damages and therefore is entitled to multiple damages under the New York False Claims Act, to

1 be determined at trial, plus a civil penalty for each violation. **COUNT SEVENTY-FIVE** 2 VIOLATION OF THE NORTH CAROLINA FALSE CLAIMS ACT 3 N.C. GEN. STAT. §1-607(a)(1) 4 366. Relator incorporates by reference the allegations set forth in the 5 foregoing paragraphs as though fully set forth herein. 6 367. This is a claim for penalties and treble damages under the North 7 Carolina False Claims Act. 8 368. As set forth above, from at least 2011 through the present, Defendants 9 knowingly presented or caused to be presented to the State of North Carolina false 10 11 or fraudulent claims for payment or approval in violation of N.C. Gen. Stat. §1-607(a)(1). 12 369. By virtue of the false or fraudulent claims submitted or caused to be 13 submitted by Defendants, the State of North Carolina suffered actual damages and 14 therefore is entitled to multiple damages under the North Carolina False Claims Act, 15 to be determined at trial, plus a civil penalty for each violation. 16 17 **COUNT SEVENTY-SIX** VIOLATION OF THE NORTH CAROLINA FALSE CLAIMS ACT 18 19 N.C. GEN. STAT. $\S1-607(a)(2)$ 370. Relator incorporates by reference the allegations set forth in the 20 foregoing paragraphs as though fully set forth herein. 21 371. This is a claim for penalties and treble damages under the North 22 23 Carolina False Claims Act. 372. As set forth above, from at least 2011 through the present, Defendants 24 knowingly made, used, or caused to be made or used false records or statements 25 material to a false or fraudulent claim submitted to the State of North Carolina in 26 27 violation of N.C. Gen. Stat. §1-607(a)(1).

28

373. By virtue of the false or fraudulent claims submitted or caused to be

submitted by Defendants, the State of North Carolina suffered actual damages and therefore is entitled to multiple damages under the North Carolina False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTY-SEVEN

VIOLATION OF THE NORTH CAROLINA FALSE CLAIMS ACT

N.C. GEN. STAT. $\S1-607(a)(3)$

- 374. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 375. This is a claim for penalties and treble damages under the North Carolina False Claims Act.
- 376. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the North Carolina False Claims Act in violation of N.C. Gen. Stat. §1-607(a)(1).
- 377. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of North Carolina suffered actual damages and therefore is entitled to multiple damages under the North Carolina False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTY-EIGHT

VIOLATION OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT 63 OKLA. STAT. §5053.1B(1)

- 378. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 379. This is a claim for penalties and treble damages under the Oklahoma Medicaid False Claims Act.
- 380. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Oklahoma false or fraudulent claims for payment or approval in violation of 63 Okla. Stat. §5053.1B(1).
 - 381. By virtue of the false or fraudulent claims submitted or caused to be

submitted by Defendants, the State of Oklahoma suffered actual damages and therefore is entitled to multiple damages under the Oklahoma Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTY-NINE

VIOLATION OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT 63 OKLA. STAT. §5053.1B(2)

- 382. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 383. This is a claim for penalties and treble damages under the Oklahoma Medicaid False Claims Act.
- 384. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Oklahoma in violation of 63 Okla. Stat. §5053.1B(2).
- 385. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Oklahoma suffered actual damages and therefore is entitled to multiple damages under the Oklahoma Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY

VIOLATION OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT 63 OKLA. STAT. §5053.1B(3)

- 386. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 387. This is a claim for penalties and treble damages under the Oklahoma Medicaid False Claims Act.
- 388. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Oklahoma Medicaid False Claims Act in violation of 63 Okla. Stat. §5053.1B(3).

389. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Oklahoma suffered actual damages and therefore is entitled to multiple damages under the Oklahoma Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY-ONE

VIOLATION OF THE RHODE ISLAND FALSE CLAIMS ACT

R.I. GEN. LAWS §9-1.1-3(a)(1)

- 390. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 391. This is a claim for penalties and treble damages under the Rhode Island False Claims Act.
- 392. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Rhode Island false or fraudulent claims for payment or approval in violation of R.I. Gen. Laws §9-1.1-3(a)(1).
- 393. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Rhode Island suffered actual damages and therefore is entitled to multiple damages under the Rhode Island False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY-TWO

VIOLATION OF THE RHODE ISLAND FALSE CLAIMS ACT

R.I. GEN. LAWS §9-1.1-3(a)(2)

- 394. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 395. This is a claim for penalties and treble damages under the Rhode Island False Claims Act.
- 396. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements

material to a false or fraudulent claim submitted to the State of Rhode Island in violation of R.I. Gen. Laws §9-1.1-3(a)(2).

397. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Rhode Island suffered actual damages and therefore is entitled to multiple damages under the Rhode Island False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY-THREE

VIOLATION OF THE RHODE ISLAND FALSE CLAIMS ACT R.I. GEN. LAWS §9-1.1-3(a)(3)

- 398. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 399. This is a claim for penalties and treble damages under the Rhode Island False Claims Act.
- 400. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Rhode Island False Claims Act in violation of R.I. Gen. Laws §9-1.1-3(a)(3).
- 401. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Rhode Island suffered actual damages and therefore is entitled to multiple damages under the Rhode Island False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY-FOUR

VIOLATION OF THE TENNESSEE FALSE CLAIMS ACT

TENN. CODE ANN. §4-18-103(a)(1)

- 402. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 403. This is a claim for penalties and treble damages under the Tennessee False Claims Act.
 - 404. As set forth above, from at least 2011 through the present, Defendants

knowingly presented or caused to be presented to the State of Tennessee false or fraudulent claims for payment or approval in violation of Tenn. Code Ann. §4-18-103(a)(1).

405. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Tennessee suffered actual damages and therefore is entitled to multiple damages under the Tennessee False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY-FIVE

VIOLATION OF THE TENNESSEE FALSE CLAIMS ACT

TENN. CODE ANN. §4-18-103(a)(2)

- 406. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 407. This is a claim for penalties and treble damages under the Tennessee False Claims Act.
- 408. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Tennessee in violation of Tenn. Code Ann. §4-18-103(a)(2).
- 409. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Tennessee suffered actual damages and therefore is entitled to multiple damages under the Tennessee False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY-SIX

VIOLATION OF THE TENNESSEE FALSE CLAIMS ACT

TENN. CODE ANN. §4-18-103(a)(3)

- 410. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
 - 411. This is a claim for penalties and treble damages under the Tennessee

False Claims Act.

- 412. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Tennessee False Claims Act in violation of Tenn. Code Ann. §4-18-103(a)(3).
- 413. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Tennessee suffered actual damages and therefore is entitled to multiple damages under the Tennessee False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY-SEVEN

VIOLATION OF THE TENNESSEE MEDICAID FALSE CLAIMS ACT TENN. CODE ANN. §71-5-182(a)(1)(A)

- 414. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 415. This is a claim for penalties and treble damages under the Tennessee Medicaid False Claims Act.
- 416. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Tennessee false or fraudulent claims for payment or approval in violation of Tenn. Code Ann. §71-5-182(a)(1)(A).
- 417. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Tennessee suffered actual damages and therefore is entitled to multiple damages under the Tennessee Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY-EIGHT

VIOLATION OF THE TENNESSEE MEDICAID FALSE CLAIMS ACT TENN. CODE ANN. §71-5-182(a)(1)(B)

418. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

- 419. This is a claim for penalties and treble damages under the Tennessee Medicaid False Claims Act.
- 420. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Tennessee in violation of Tenn. Code Ann. §71-5-182(a)(1)(B).
- 421. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Tennessee suffered actual damages and therefore is entitled to multiple damages under the Tennessee Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY-NINE

VIOLATION OF THE TENNESSEE MEDICAID FALSE CLAIMS ACT TENN. CODE ANN. §71-5-182(a)(1)(C)

- 422. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 423. This is a claim for penalties and treble damages under the Tennessee Medicaid False Claims Act.
- 424. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Tennessee Medicaid False Claims Act in violation of Tenn. Code Ann. §71-5-182(a)(1)(C).
- 425. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Tennessee suffered actual damages and therefore is entitled to multiple damages under the Tennessee Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETY

VIOLATION OF THE TEXAS MEDICAID FRAUD PREVENTION LAW

TEX. HUM. RES. CODE §36.002(1)

- 426. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 427. This is a claim for penalties and treble damages under the Texas Medicaid Fraud Prevention Law.
- 428. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Texas false or fraudulent claims for payment or approval in violation of Tex. Hum. Res. Code §36.002(1).
- 429. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Texas suffered actual damages and therefore is entitled to multiple damages under the Texas Medicaid Fraud Prevention Law, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETY-ONE

VIOLATION OF THE TEXAS MEDICAID FRAUD PREVENTION LAW TEX. Hum. Res. Code §36.002(4)(A)

- 430. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 431. This is a claim for penalties and treble damages under the Texas Medicaid Fraud Prevention Law.
- 432. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Texas in violation of Tex. Hum. Res. Code §36.002(4)(A).
- 433. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Texas suffered actual damages and therefore

is entitled to multiple damages under the Texas Medicaid Fraud Prevention Law, to 1 be determined at trial, plus a civil penalty for each violation. 2 3 **COUNT NINETY-TWO** VIOLATION OF THE TEXAS MEDICAID FRAUD PREVENTION LAW 4 TEX. HUM. RES. CODE §36.002(9) 5 434. Relator incorporates by reference the allegations set forth in the 6 foregoing paragraphs as though fully set forth herein. 7 435. This is a claim for penalties and treble damages under the Texas 8 9 Medicaid Fraud Prevention Law. 436. As set forth above, from at least 2011 through the present, Defendants 10 knowingly conspired together to commit violations of the Texas Medicaid Fraud 11 Prevention Law in violation of Tex. Hum. Res. Code §36.002(9). 12 437. By virtue of the false or fraudulent claims submitted or caused to be 13 submitted by Defendants, the State of Texas suffered actual damages and therefore 14 15 is entitled to multiple damages under the Texas Medicaid Fraud Prevention Law, to be determined at trial, plus a civil penalty for each violation. 16 17 **COUNT NINETY-THREE** VIOLATION OF THE VERMONT FALSE CLAIMS ACT 18 19 32 VT. STAT. ANN. §631(a)(1) 438. Relator incorporates by reference the allegations set forth in the 20 foregoing paragraphs as though fully set forth herein. 21 439. This is a claim for penalties and treble damages under the Vermont 22 23 False Claims Act. 440. As set forth above, from at least 2011 through the present, Defendants 24 knowingly presented or caused to be presented to the State of Vermont false or 25 fraudulent claims for payment or approval in violation of Vt. Stat. Ann. §631(a)(1). 26 27 441. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Vermont suffered actual damages and 28

therefore is entitled to multiple damages under the Vermont False Claims Act, to be 1 2 determined at trial, plus a civil penalty for each violation. 3 **COUNT NINETY-FOUR** VIOLATION OF THE VERMONT FALSE CLAIMS ACT 4 32 VT. STAT. ANN. §631(a)(2) 5 442. Relator incorporates by reference the allegations set forth in the 6 foregoing paragraphs as though fully set forth herein. 7 443. This is a claim for penalties and treble damages under the Vermont 8 9 False Claims Act. 444. As set forth above, from at least 2011 through the present, Defendants 10 knowingly made, used, or caused to be made or used false records or statements 11 material to a false or fraudulent claim submitted to the State of Vermont in violation 12 of Vt. Stat. Ann. §631(a)(2). 13 445. By virtue of the false or fraudulent claims submitted or caused to be 14 submitted by Defendants, the State of Vermont suffered actual damages and 15 16 therefore is entitled to multiple damages under the Vermont False Claims Act, to be determined at trial, plus a civil penalty for each violation. 17 **COUNT NINETY-FIVE** 18 VIOLATION OF THE VERMONT FALSE CLAIMS ACT 19 32 VT. STAT. ANN. §631(a)(12) 20 446. Relator incorporates by reference the allegations set forth in the 21 foregoing paragraphs as though fully set forth herein. 22 447. This is a claim for penalties and treble damages under the Vermont 23 24 False Claims Act. 448. As set forth above, from at least 2011 through the present, Defendants 25 knowingly conspired together to commit violations of the Vermont False Claims Act 26 27 in violation of Vt. Stat. Ann. §631(a)(12). 449. By virtue of the false or fraudulent claims submitted or caused to be

28

submitted by Defendants, the State of Vermont suffered actual damages and therefore is entitled to multiple damages under the Vermont False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETY-SIX

VIOLATION OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT Va. Code Ann. §8.01-216.3(A)(1)

- 450. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 451. This is a claim for penalties and treble damages under the Virginia Fraud Against Taxpayers Act.
- 452. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the Commonwealth of Virginia false or fraudulent claims for payment or approval in violation of Va. Code Ann. §8.01-216.3(A)(1).
- 453. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the Commonwealth of Virginia suffered actual damages and therefore is entitled to multiple damages under the Virginia Fraud Against Taxpayers Act, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETY-SEVEN

VIOLATION OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT Va. Code Ann. §8.01-216.3(A)(2)

- 454. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 455. This is a claim for penalties and treble damages under the Virginia Fraud Against Taxpayers Act.
- 456. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the Commonwealth of Virginia

in violation of Va. Code Ann. §8.01-216.3(A)(2).

457. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the Commonwealth of Virginia suffered actual damages and therefore is entitled to multiple damages under the Virginia Fraud Against Taxpayers Act, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETY-EIGHT

VIOLATION OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT Va. Code Ann. §8.01-216.3(A)(3)

- 458. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 459. This is a claim for penalties and treble damages under the Virginia Fraud Against Taxpayers Act.
- 460. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Virginia Fraud Against Taxpayers Act in violation of Va. Code Ann. §8.01-216.3(A)(3).
- 461. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the Commonwealth of Virginia suffered actual damages and therefore is entitled to multiple damages under the Virginia Fraud Against Taxpayers Act, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETY-NINE

VIOLATION OF THE WASHINGTON STATE MEDICAID FRAUD FALSE CLAIMS ACT

WASH REV. CODE §74.66.020(1)(a)

- 462. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 463. This is a claim for penalties and treble damages under the Washington State Medicaid Fraud False Claims Act.
 - 464. As set forth above, from at least 2011 through the present, Defendants

knowingly presented or caused to be presented to the State of Washington false or fraudulent claims for payment or approval in violation of Wash. Rev. Code §74.66.020(1)(a).

465. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Washington suffered actual damages and therefore is entitled to multiple damages under the Washington State Medicaid Fraud False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT ONE-HUNDRED

VIOLATION OF THE WASHINGTON STATE MEDICAID FRAUD FALSE CLAIMS ACT

WASH. REV. CODE §74.66.020(1)(b)

- 466. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 467. This is a claim for penalties and treble damages under the Washington State Medicaid Fraud False Claims Act.
- 468. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Washington in violation of Wash. Rev. Code §74.66.020(1)(b).
- 469. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Washington suffered actual damages and therefore is entitled to multiple damages under the Washington State Medicaid Fraud False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT ONE-HUNDRED-AND-ONE VIOLATION OF THE WASHINGTON STATE MEDICAID FRAUD FALSE CLAIMS ACT

WASH. REV. CODE §74.66.020(1)(c)

- 470. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.
- 471. This is a claim for penalties and treble damages under the Washington State Medicaid Fraud False Claims Act.
- 472. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Washington State Medicaid Fraud False Claims Act in violation of Wash. Rev. Code §74.66.020(1)(c).
- 473. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Washington suffered actual damages and therefore is entitled to multiple damages under the Washington State Medicaid Fraud False Claims Act, to be determined at trial, plus a civil penalty for each violation.

PRAYER FOR RELIEF

WHEREFORE, the United States and Relator demand that judgment be entered against Defendants and in favor of the Relator and the United States as follows:

On the first through one-hundred-and-first causes of action under the federal False Claims Act (and as amended and equivalent state statutes), a judgment for the amount of the United States' and the States' damages, multiplied by three as required by law, and such civil penalties as are permitted or required by law; the maximum share amount allowed pursuant to 31 U.S.C. § 3730(d) and applicable State laws; all costs and expenses of this action, including attorney fees, expenses and costs as permitted by 31 U.S.C. § 3730(d) and applicable State laws; and all such other relief as may be just and proper.

1	Dated: July 23, 2018	Respectfully submitted,
2		
3		pu / www
4		KURT RAMLO LEVENE, NEALE, BENDER, YOO & BRILL L.L.P.
5		Ligary, when I'Ve from
6		KURTRAMIO
7 8		Gregory M. Utter * (OH Bar No. 0032528) Joseph M. Callow, Jr. * (OH Bar No. 0061814) KEATING MUETHING & KLEKAMP PLL
9		Toel Di Herch Pipilmon.
10		KURTRAM 10
11		Joel D. Hesch * (DC Bar No. 421822) THE HESCH FIRM, LLC
12		
13		ATTORNEYS FOR RELATORS, NICK FINCH and NICK SACCOMANNO
14		* Pro hac vice applications forthcoming
15		
16		
17		
18		
19		
20		
21		
22	,	
23		
24		
25		
26		
27		
28		
	II.	

REQUEST FOR TRIAL BY JURY Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury. Respectfully submitted, Dated: July 23, 2018 KURT RAMIZO EVENE, WEALE, BENDER, YOO & BRILL Gregory M. Utter * (OH Bar No. 0032528)
Joseph M. Callow, Jr. * (OH Bar No. 0061814)
KEATING MUETHING & KLEKAMP PLL Joel D. Hesch * (DC Bar No. 421822) THE HESCH FIRM, LLC ATTORNEYS FOR RELATORS, NICK FINCH and NICK SACCOMANNO * Pro hac vice applications forthcoming

Exhibit A

One Standard
Across the Care
Continuum





Breaking Down Barriers to Care

The Institute of Healthcare Improvement's triple aim designed to push quality initiatives while simultaneously fostering marketplace efficiencies—has rippled across the healthcare continuum. Advancement simply for the sake of change is not enough; it must enhance healthcare in some way. Improvements must be quantifiable, as well as qualifiable. Care must be coordinated. Every clinician must manage greater risk as patients present with multiple comorbidities. To navigate this dynamic, providers across the spectrum—from the smallest practices to the largest health systems—need allies capable of helping them remain ahead of the rapidly shifting environment while ensuring the highest quality of care for patients. 79

Nihon Kohden is that ally.

A leader in precision medical products and services, only Nihon Kohden offers reliable, integrated multimodality products that serve patients across all care areas. We bring quality clinical solutions that provide access to a deeper, more comprehensive level of information, enabling more accurate diagnoses and ultimately, better outcomes.

Premium-as-Standard Design

We belive every patient deserves the highest standard of care. Nihon Kohden's premium-as-standard philosophy is the belief that every monitor should be fully appointed with features—both standard and premium—unlocked and ready to use at a moment's notice. This ensures that our technology can be employed in the broadest range of acuity levels and seamlessly transition between care areas as patient need dictates.

The BSM-6000 series of monitors offer unrivaled technology that works across the healthcare continuum and realizes our premium-as-standard philosophy, allowing providers to deliver care without compromise.

Some of our premium-as-standard capabilities include:

- Comprehensive arrhythmia detection and recall, including advanced Atrial Fibrillation algorithm
- Multi-waveform/multi-parameter full disclosure
- ST segment analysis as well as diagnostic
 12 lead ECG capability
- Drug, hemodynamic and pulmonary calculations



BSM-6301 10.4-inch LCD

BSM-65(12.1-inch LC Nihon Kohden's unique Smart Cable™ technology miniaturizes circuits found in traditional modules and embeds that circuitry into a Smart Patient Cable. When you plug a Smart Cable into a Multiport, the associated parameter is automatically detected, displayed and measured. With this technology, you'll get parameter flexibility at a significantly reduced cost with seamless and immediate access to blood pressure, cardiac output, EtCO₂, temperature, BIS, EEG and more, when and where you need it for rapid clinical assessment across care areas.





27

CD



BSM-6701 15-inch LCD



Arrhythmia

The BSM-6000 Series provides high accuracy multi-lead arrhythmia detection and storage of over 16,000 arrhythmia events. Each event is time-linked to the full disclosure waveforms to determine what led up to, and what followed, the captured event.



Full Disclosure

Full disclosure waveforms allow you to validate alarm and numeric findings and to make treatment decisions based on more accurate monitored data. The BSM-6000 Series provides storage and review capabilities at the bedside monitor that are typically found only in a central station.



ST Template

Multi-lead ST segment monitoring provides you with continuous oversight to transient changes in your patients' cardiac condition and are stored minute-to-minute in the monitor for comparison.

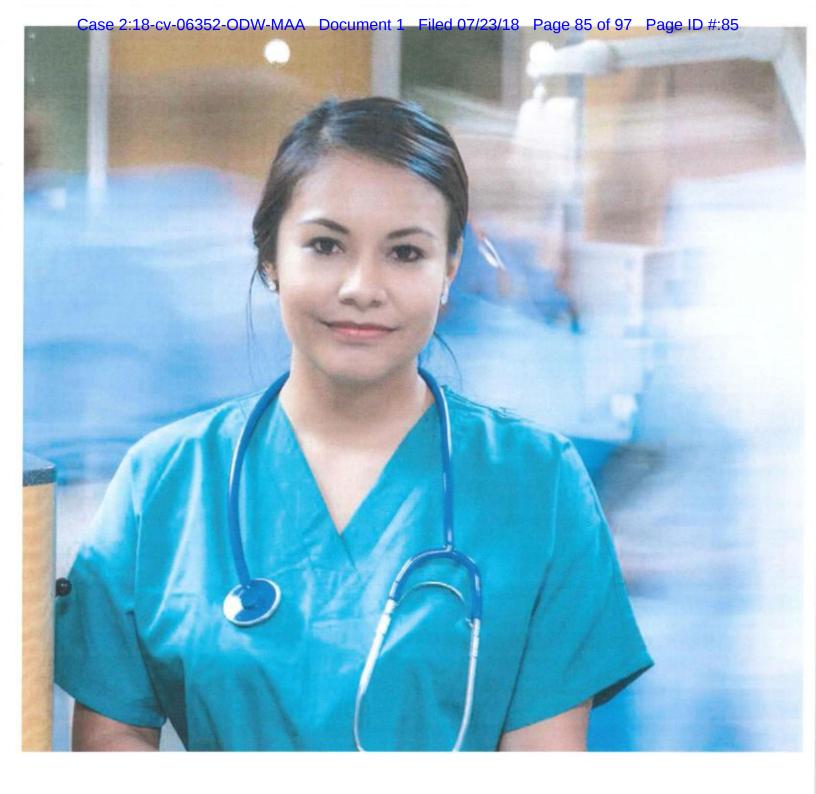
Redefining Transport

Continuity of monitored care during transport ensures the highest quality of care for patients. The unique design of Nihon Kohden's BSM-1700 Transport monitor and the BSM-6000 redefines transport monitoring. Simply disconnect the BSM-1700 Transport monitor from the BSM-6000 monitor or Data Acquisition Unit and your patient can be transported with all monitoring capabilities remaining the same. When the patient is transferred to their new care setting and the BSM-1700 is reconnected to another BSM-6000 or Life Scope G9 monitor and patient information, including full disclosure, is uploaded to the new bedside display creating one seamless, reliable patient record enhancing workflow and care coordination. Patient transport using the wireless option for the BSM-1700 provides uninterrupted Central Station Monitoring and WLAN Transport that manages your patient data automatically.





One additional benefit of the Data Acquisition Unit is that it can be extended via an umbilical cord to be located on a bed rail, gurney or IV pole next to the patient. This alleviates the hassles associated with cable management at the bedside. Since the Data Acquisition Unit contains user function keys, it can be placed on either side of the patient for optimal clinical workflow efficiency.





MMLB 011 (C)-CO-1072

Different Thinking for Better Healthcare.

Different Trinking for Better Healthcare is a registered trademark of Nihan Kabden.

Exhibit B

Transport Monitor BSM-1700



One Standard of Care Across the Continuum of Care



- Functions as a compact stand-alone monitor, transport monitor or as an Input Unit for a BSM-6000, BSM-9000 or Life Scope G9 series bedside monitor
- Allows seamless transfer of data between bedside monitors and central stations
- · 5 hour battery life
- · Lightweight at only 3.4 lbs
- · High-resolution touch screen display
- · Comprehensive data storage:
 - O Up to 72 hours full disclosure waveforms
 - Tabular & graphical trends
 - Arrhythmia recall files
 - ST recall files

Specifications

Transport Monitor BSM-1700

BSM-1700

DISPLAY

Display Size:

5.7" Touch Screen Display

Display Modes:

Standard, Transport

Maximum Number of

Waveform Traces:

9 traces

Display Waveforms:

ECG (up to 12 leads), respiration, IBP (up to 3 traces). SpO2 pulse wave, CO2, CO thermodilution Curve, BIS

Numerical

Data Display:

Heart rate, VPC rate, ST level, respiration rate, SpO₂, pulse rate, temperature, NIBP (systolic, diastolic, MAP), IBP (systolic, diastolic, mean), EtCO₂, FiCO₂, cardiac output, cardiac index, injectate temperature, blood temperature,

BIS, SEF95, SR, EMG, SQI

ALARMS

Alarm Items:

Upper/lower limits alarm, arrhythmia alarm

Alarm Levels:

Crisis (red blinking), Warning (yellow blinking),

Advisory (yellow or blue light)

Alarm Indication:

Alarm indicator, highlighted message, alarm sound

Alarm Suspend:

1, 2, or 3 min or off

PARAMETERS

ECG:

Number of electrodes: 3, 6 or 10

Frequency response:

Diagnosis mode: 0.05 to 150 Hz Monitor mode: 0.3 to 40 Hz Maximum filter mode: 1 to 18 Hz

Heart Rate Counting range: 0, 15 to 300 beats/min Arrhythmia analysis method: Multi-template matching

software algorithm

VPC counting rate: 0 to 99 VPCs/min

Arrhythmia alarms: ASYSTOLE, VF, VT, V BRADY, EXT TACHY, EXT BRADY, SV TACHY, VPC RUN, TACHYCARDIA, BRADYCARDIA, COUPLET, EARLY VPC, MULTIFORM, V RHYTHM, PAUSE, BIGEMINY, TRIGEMINY, VPC, IRREGULAR RR, PACER NON-CAPTURE, PROLONGED RR, NO PACER

PULSE, (NOISE, CHECK ELECTRODES, LEARNING)

ST Level Measurement:

Number of measurement channels: Up to 12

Measuring range: ±2.5 mV

Respiration (Impedance Pneumography):

Measuring range: 0 to 150 breaths/min

SpO2:

Measuring Technology: Nihon Kohden, Massimo or Nellcor Measuring Display Range: 0 to 100% (70 to 100% at

specified accuracy)

Pulse rate from \$pO₂ Range: 25 to 300 beats/min (varies by SpO₂ technology)

Non Invasive Blood

Pressure, NIBP:

Measuring method: Oscillometric Cuff Pressure display range: 0 to 300 mmHg

Invasive Blood Pressure, IBP:

Number of channels: Up to 3

Measuring range: -50 to 300 mmHg

Pulse rate from IBP range: 0, 30 to 300 beats/min

Temperature:

Measuring range: 0 to 45°C

Number of channels: 2 maximum

Cardiac Output:

Measuring method: Thermodilution method Measuring range: Injectate temperature (Ti):

0°C to 27°C

Blood temperature (Tb): 15°C to 45°C Thermodilution curve (delta Tb): 0°C to 2.5°C Cardiac output (CO): 0.5 to 20 L/min

BIS:

Input channels: 1 or 2 (depends on the BIS

sensor type)

Measuring parameters: Bispectral Index(BIS), 95% Spectral Edge Frequency (SEF95), Suppression Ratio (SR), EMG, Signal Quality Index (SQI)

CO2:

CO₂ measuring range: 0 to 100 mmHa

Respiration rate counting range: 3 to 150 breaths min

STORED PATIENT DATA

Trendgraph:

Trend parameters: All monitored parameters

Trend display time: Up to 72 hours

Vital Signs List:

Trend parameters: All monitored parameters Data Storage: Periodic: 4320 (1 per minute for

72 hours)

NIRP:

2,048 files

Full Disclosure:

Storage time: Up to 72 hours Number of entries: 32,768 files

Number of Waveforms stored: 5 maximum

Alarm History:

Hemodynamics Trend Table:

Number of entries: 2 048 files

Arrhythmia Recall:

Number of files: 32,768 files

ST Recall:

Number of files: 4,320 files (1 per minute for 72 hours)

for all monitoring leads

12 Lead

Interpretive Recall:

Number of files: 18 files

POWER REQUIREMENT DC (SB-170P Lithium

Ion Battery Pack): 9.0 to 12.6 V

Battery operation time: 5 hours

With SC-170R Cradle: Line voltage AC 100V to 240V

Line Frequency:

50 or 60 Hz

Power Input:

80 VA

DIMENSIONS AND WEIGHT

Dimensions:

147W× 194H × 94D mm

Weight:

1.57 kg with battery pack

Bedside Monitor Specification Comparison

		Accut	Accute Care/Hospital Market	Aarket		ASC Market ONLY
	69	TR6000	TR6000	TR6000	TPM	TR3000
	CSM-1901	BSM-6700	BSM-6500	BSM-6300	BSM-1700	BSM-3500
		100	*	8.8		
			Display			Display
Type	Color LCD	Color LCD	Color LCD	Color LCD	Color LCD	Color LCD
adf.	21.5"	15"	12.1"	10.4"	5.7"	12"
Resolution	1920 × 1080	1024 × 768	800 × 600	800 × 600	640 × 480	800 × 600
Number Of Traces	17	15	15	15	9 (12 for ECG)	14
Touchscreen Operation	Yes	Yes	Yes	Yes	Yes	Yes
User Programmable Multi-Function Keys	Yes, 20	Yes, 4	Yes, 4	Yes, 4	Yes, 2	Yes, 4
Remote Control	Yes, Optional	Yes, Optional	Yes, Optional	Yes, Optional	N/A	Yes, Optional
			Parameters			Parameters
ECG Leads on Main Screen	Up to 12	Up to 3	Up to 3	Up to 3	Up to 3	Up to 3
Number of Viewable ECG Leads (any screen)	12	12	12	12	12	12
Number Of ECG Electrodes	3, 6 or 10	3, 6 or 10	3, 6 or 10	3, 6 or 10	3, 6 or 10	3, 6, or 10
SpO ₂ , NIBP	Yes (Configured)	Yes (Configured)	Yes (Configured)	Yes (Configured)	Yes (Configured)	Yes (Configured)

us.nihonkohden.com

NIHON KOHDEN

MMLB 093[D]-CO-1274

Different Thinking for Better Healthcare.®

Z
9
Z
오
Z

us.nihonkohden.com

	00	TOCOOL	-			The state of the s
	65	IKPOOD	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	1R6000	TPM	TR3000
	CSM-1901	BSM-6700	BSM-6500	BSM-6300	BSM-1700	BSM-3500
			Parameters			Parameters
IBP, CO ₂ , Cardiac Output	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)
FiO ₂ . Thermistor Respiration	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)
Temperature	Yes 2 Configured 2 Smart Cable	Yes 2 Configured	Yes 2 Configured 2 Smart Cable			
BIS	Yes (Smart Modular Cable, or External Device)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable, or External Device)			
			Multi-Connectors			Multi-Connectors
Number of Multi- Connectors	7 Options to Expand to 11	3 or 7 Depending upon Model	3 or 7 Depending upon Model	1, 3 or 7 Depending upon Model	т	2
			Recorder			Recorder
3 Channel	Yes, Optional	Yes, Optional	Yes, Optional	Yes, Optional	No	Yes, Optional
			Battery Operation			Battery Operation
Standard or Optional	Standard	Standard	Standard	Optional	Optional	Optional
Operation Time	1 battery = 3 min	2 batteries = 2 hrs	2 batteries = 3 hrs	2 batteries = 3 hrs	5 hrs	1 battery = 1.5 hrs

	69	TR6000	TR6000	TR6000	TPM	TR3000
	CSM-1901	BSM-6700	BSM-6500	BSM-6300	BSM-1700	BSM-3500
			Monitor Functions			
Full Disclosure	5 Waves for 168 Hours, 8 Waves for 96 Hours, 35 Waves for 24	5 Waves 72 Hours Standard (24 Hours if X-Port	5 Waves 72 Hours Standard			
Graphical Trends	Hours 168 Hours	Data is on) 72 Hours	Data is on) 72 Hours	Data is on) 72 Hours	Data is on) 72 Hours	72 Hours
Tabular Trends	168 Hours for up to 108 Parameters	4,320 Files (72 Hours, 24 Hours if X-Port Data is On)	4,320 Files (72 Hours, 24 Hours if X-Port Data is On)	4,320 Files (72 Hours, 24 Hours if X-Port Data is On)	4,320 Files (72 Hours, 24 Hours if X-Port Data is On)	4,320 Files (72 Hours)
NIBP Tabular Trends	1,008 Files (168 Hours)	1,024 Files (72 hours, 24 hours if X-Port Data is on)	1,024 Files (72 hours, 24 hours if X-Port Data is on)	1,024 Files (72 hours, 24 hours if X-Port Data is on)	1,024 Files (72 Hours, 24 Hours if X-Port Data is on)	1,024 Files (72 Hours)
Arrhythmia Recall	60,480 Files (168 Hours)	16,348 Files (72 Hours)	16,348 Files (72 Hours)	16,348 Files (72 Hours)	24,576 Files (72 Hours)	16,348 Files (72 Hours)
Alarm History	302,400 Files for the Past (168 Hours)	16,348 Files (72 Hours)	16,348 Files (72 Hours)	16,348 Files (72 Hours)	16,348 Files (72 Hours)	16,348 Files (72 Hours)
ST Recall	10,080 Files	4,320 Files, 12 Leads, Standard (72 Hours, 24 Hours if X-Port Data is On)	4,320 Files, 12 Leads, Standard (72 Hours, 24 Hours if X-Port Data is On)	4,320 Files, 12 Leads, Standard (72 Hours, 24 Hours if X-Port Data is On)	4,320 Files, 12 Leads, Standard (72 Hours, 24 Hours if X-Port Data is On)	4,320 Files, 12 Leads, Standard

mo
ohden.c
nihonko
us.r
Z
CHO)
ON
Ē

	69	TR6000	TR6000	TR6000	TPM	TR3000
	CSM-1901	BSM-6700	BSM-6500	BSM-6300	BSM-1700	BSM-3500
			Monitor Functions			
			and			Monitor Functions
Drug Calculations	Yes	Yes	Yes	Yes	N/A	Yes
Interpretive 12 Lead ECG Storage	672 Files (72 Hours)	18 Files (72 Hours)	18 Files (72 Hours)	18 Files (72 Hours)	18 Files (72 Hours)	18 Files (72 Hours)
Hemodynamic Calculations	1,008 Files	1,024 Files	1,024 Files	1,024 Files	1,536 Files	1,024 Files
Pulmonary Calculations	1,008 Files	512 Files (72 Hours)	512 Files (72 Hours)	512 Files (72 Hours)	N/A	512 Files (72 Hours)
Interbed Display	Yes, with 16 Bed Views	Yes, with 16 Bed Views	Yes, with 16 Bed Views	Yes, with 16 Bed Views	Yes, with 9 Bed Views	Yes, with 20 Dual Bed Views
MAC Display (minimum alveolar concentration)	Yes	Yes	Yes	Yes	N/A	Yes
Data Transport with Upload to CNS	Yes	Yes	Yes	Yes	Yes	ON
			ECG			ECG
Multi-Lead Arrhythmia Processing	Yes, Dual Lead	Yes, Dual Lead	Yes, Dual Lead	Yes, Dual Lead	Yes, Dual Lead	Yes, Dual Lead
Interpretive 12-Lead ECG	Yes	Yes	Yes	Yes	Yes	Yes

	0.50	TDEOOO	TDCOOO	TDCOOO	TON	20000
	60	DODONI	INDUON	IKPOOO	FW	1K3000
	CSM-1901	BSM-6700	BSM-6500	BSM-6300	BSM-1700	BSM-3500
			Sp02			Sp02
SpO2 Technology	Nellcor OxyMax, Masimo SET or Nihon Kohden SpO2	Nellcor OxyMax, Masimo SET or Nihon Kohden SpO2	Nellcor OxyMax, Masimo SET or Nihon Kohden SpO2			
			NIBP			NIBP
Method	Oscillometric	Oscillometric	Oscillometric	Oscillometric	Oscillometric	Oscillometric
Special NIBP Modes	Staged Interval and Venous Puncture	Staged Interval and Venous Puncture	Staged Interval and Venous Puncture	Staged Interval and Venous Puncture	Staged Interval and Venous Puncture	Staged Interval and Venous Puncture
		ıl	Invasive Pressure (IBP)			Invasive Pressure (IBP)
Number of Channels	Up to 8 Depending on Number of Multiport Connectors	Up to 7 Depending on Number of Multiport Connectors	Up to 7 Depending on Number of Multiport Connectors	Up to 7 Depending on Number of Multiport Connectors	Up to 3	Up to 2
CPP Display (Cerebral Perfusion Pressure for ICP)	Yes	Yes	Yes	Yes	ON	Yes
			Communications			Communications
Hardwired Central Communications	Yes	Yes	Yes	Yes	Yes, when using SC-170R Docking Station	Yes

Different Thinking for Better Healthcare.®

us.nihonkohde	
NIHON KOHDEN	

	69	TR6000	TR6000	TR6000	TPM	TR3000
	CSM-1901	BSM-6700	BSM-6500	BSM-6300	BSM-1700	BSM-3500
			Communications			Communications
W-LAN (Wireless) Central Communications	N/A	Optional, Requires QI-420-PA	Optional, Requires QI-420-PA	Optional, Requires QI-420-PA	Yes (QI-170P)	Optional, Requires QI-420-PA
ECG Output	Yes	Yes	Yes	Yes	Yes	Yes
IBP Output	Yes	Yes	Yes	Yes	Yes	Yes
External monitor output	Yes, Using Data Export Cable YS-094P2	Optional, Requires QI-671P and Standard Video Cable	Optional, Requires QI-671P and Standard Video Cable	Optional, Requires QI-671P and Standard Video Cable	°Z	Optional. Requires QI-372P
Laser Printer Documentation without Central	Yes	Yes	Yes	Yes	Yes, when using SC-170R Docking Station or WLAN	Yes
Laser Printer Documentation with Central	Yes	Yes	Yes	Yes	Yes, when using SC-170R Docking Station or WLAN	Yes
USB Interface to External Devices	Yes	Optional, Requires QI-672P. Supports USB Mouse or Bar Code Scanner.	Optional, Requires QI-672P. Supports USB Mouse Supports USB Mouse or Bar Code Scanner. or Bar Code Scanner.	Optional, Requires QI-672P. Supports USB Mouse or Bar Code Scanner.	°Z	Optional with QI Equipped Models. No USB.

Different Thinking for Better Healthcare.®

	٤	
	ō	
	Q	
	c	
ı,	<u>Φ</u>	
	ဗ္	
ľ	ō	
	ž	
	듯	
	ĕ	
•	=	
	S	
	ij	

_
2
8
I
9
=
6
兰
7
V

	69	TR6000	TR6000	TR6000	TPM	TR3000
	CSM-1901	BSM-6700	BSM-6500	BSM-6300	BSM-1700	BSM-3500
i 177						
		Ex	External Device Interfaces	ses		External Device Interfaces
Maximum Number of External Devices	3 Standard on G9 CPU, 5 with DAU Additional 6 with Junction Box	5 (Optional, 1 with QI-671P and 4 with QI-672P)	5 (Optional, 1 with QI-671P and 4 with QI-672P)	1 with QI-632P or 3 with QI-634P	N/A	2 (Optional with QI Equipped models)
Ventilators	Yes	Yes	Yes	Yes	N/A	Yes
CCO/SvO2	Yes	Yes	Yes	Yes	N/A	Yes
Oridion MicroStream CO ₂	Yes	Yes	Yes	Yes	N/A	Yes
SpO ₂ for dual SpO ₂	Yes	Yes	Yes	Yes	Yes, with JL-500 P1	Yes
Anesthesia Carts	Yes	Yes	Yes	Yes	N/A	Yes
TcPO ₂ Units	Yes	Yes	Yes	Yes	N/A	Yes
Aspect BIS Monitor	Yes, External Interface or BISx Through Multiport Connector	Yes, External Interface or BISx Through Multiport Connector	Yes, External Interface or BISx Through Multiport Connector	Yes, External Interface or BISx Through Multiport Connector	N/A	Yes, External Interface or BISx Through Multiport Connector
Anesthetic Gas Module (AG-920RA)	Yes	Yes, Requires QF-904P Interface	Yes, Requires QF-904P Interface	Yes, Requires QF-904P Interface	N/A	Yes, Requires QF-904P Interface

	69	IKOUU	I K6000	IR6000	TPM	TR3000
	CSM-1901	BSM-6700	BSM-6500	BSM-6300	BSM-1700	BSM-3500
			Dimension and Weight	æ		Dimension and Weight
Dimensions, in. (W,H,D)	Main Unit: 16 x 12.7 x 14.4 Display: 21.5	16.4 x 15.4 x 7.5	13.5 x 13.9 x 7.2	12.4 x 12.8 x 7.4	5.8 × 7.6 × 3.7	14.5 × 12.2 × 6.7
Weight, Ibs	Main Unit: 27.5 Display: 12.1	22.7	18.3	11.7	3.5 (Including Battery)	13.6
List Price	From \$31,800.00 to \$34,000.00	From \$17,490.00 to \$26,600.00	From \$15,250.00 to \$23,200.00	From \$8,220.00 to \$12,660.00	From \$7,560.00 to \$7,830.00	From \$3,900.00 to \$6,262.00

Bedside Monitor BSM-3500



Quality Vital Sign Monitoring

- Compact, configured monitor with touchscreen display for ease of operation
- Ideal for ambulatory and specialty surgery centers
- Premium-as-standard design, providing all software options with base model
- Multiple Smart Cable™ ports for optimal parameter flexibility
- Comprehensive storage of multiple parameters to guide treatment decisions, including;
 - Arrhythmia detection and recall
 - o ST analysis and recall
 - o cap-ONE® Mainstream CO2 sensor for intubated and non-intubated patients
 - o Tabular and graphical trends
 - o Full disclosure waveforms
 - o Diagnostic 12-lead ECG

Specifications

Bedside Monitor BSM-3500

BSM-3500

DISPLAY

Display Size:

12.1" color TFT type LCD

Display

Characteristics:

Resolution: 800 x 600. Touch screen with six quick access

hard keys

Maximum Number of **Waveform Traces:**

Up to 14 traces

Display Waveforms:

ECG (up to 12), respiration, IBP (up to 2), SpO_2 pulse wave, CO_2 , BIS EEG (up to 2 traces), vent PAW, vent Flow, and CO Thermodilution curve. When gas is monitored: O₂ concentration curve, CO₂ concentration curve, anesthetic agent concentration (Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane) Analog input

Numerical Data Display:

Heart rate, VPC rate, ST level, RR respiration rate, NIBP (systolic, diastolic, mean), IBP (systolic, diastolic, mean), SpO₂, SpO₂-2, delta SpO₂, pulse rate, temperature, CO, Spo₂, spo₂, defid spo₂, pulse rule, temperature, CO, Ti (injectate temperature), Tb (blood temperature), O_2 concentration, EtCO₂, BIS, inspired/ expired N_2O concentration, inspired/ expired CO₂, inspired/ expired O_2 concentration, inspired/ expired anesthetic agent concentration (Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane), MAC (minimum alveolar concentration), Ppeak (peak airway pressure), PEEP (positive end expiratory pressure), Pmean (mean airway pressure), MV (minute volume), TVi (inspiratory tidal volume), TVe (expiratory tidal volume), C (compliance), R (airway resistance), Ri (inspiratory airway resistance). Re (expiratory airway resistance), I:E (inspiration expiration ratio), SEF (90 or 95% spectral edge frequency), MDF (median frequency), PPF (peak power frequency), TP (total power), TP power of frequency, TOF, CCO, SVRI, SVO₂, EF, ScvO₂, CCI, EDV, SVR, EDVI, PCCO, PCCI, tcPO₂, tcPCO₂, PPV, SPV

ALARMS

Alarm Items:

Vital sign alarms, arrhythmia alarms, technical alarms

and operational alarms

Alarm Levels:

Crisis (red blinking), Warning (yellow blinking), Advisory (yellow or blue light)

Alarm Indication:

Alarm indicator (360° visibility) highlighted message,

Alarm Suspend:

1, 2, or 3 min

PARAMETERS ECG:

Number of ECG waveforms channels: up to 12

Frequency response:

Diagnosis mode: 0.05 to 150 Hz Monitor mode: 0.3 to 40 Hz Maximum filter mode: 1 to 18 Hz

Heart Rate Counting range: 0, 15 to 300 beats/min Arrhythmia Analysis method: Multi-template software

algorithm

VPC counting rate: 0 to 99 VPCs/min

Arrhythmia alarms: ASYSTOLE, VF, VT, V RHYTHM, V BRADY, EXT TACHY, EXT BRADY, AF, VPC RUN, COUPLET, EARLY VPC, BIGEMINY, TRIGEMINY, FREQ VPC, PROLONGED RR, SV TACHY, TACHYCARDIA, BRADYCARDIA, VPC, MULTIFORM, IRREGULAR RR, NO PACER PULSE, PACER NON-CAPTURE,

ST Level Measurement: Number of measurement channels: up to 12

Measuring range: ±2.5 mV

Respiration

Thermistor Method): Measuring range: 0 to 150 breaths/min SpO₂: Measuring Technology: Nihon Kohden, Masimo or Nellcor

Measuring Display Range: 0 to 100% (70 to 100% at

specified accuracy)

Pulse rate from SpO₂ Range: 0, 30 to 300 beats/min

(varies by SpO₂ technology)

Non Invasive Blood Pressure, NIBP:

Measuring method: Oscillometric Cuff Pressure display range: 0 to 300 mmHa

Invasive Blood

Pressure, IBP:

Measuring range: -50 to 300 mmHa

Pulse rate display range from IBP range: 30 to 300

beats/min

Temperature: Measuring range: 0 to 45°C

Number of channels: 2 with Delta Temp

Cardiac Output: Measuring method: Thermodilution method

Measuring range: Injectate temperature (Ti): 0°C to 27°C

Blood temperature (Tb): 15°C to 45°C Thermodilution curve (delta Tb): 0°C to 2.5°C Cardiac output (CO): 0.5 to 20 L/min

Inspired Oxygen Fractional

Concentration:

Measuring range: 10 to 100%

CO2: CO₂ measuring range: 0 to 150 mmHa

Respiration rate counting range: 0 to 150 breaths/min

BIS: Input channels: 2

> Measuring parameters: Bispectral Index (BIS), 95% Spectral Edge Frequency (SEF90, SEF95)

Suppression Ratio (SR), EMG, Signal Quality Index (SQI)

STORED PATIENT DATA

Trendgraph: Trend parameters: All monitored parameters

Trend display time: Up to 72 hours

Vital Signs List: All monitored parameters for up to 72 hours (1 per minute

for 72 hours)

NIBP: Number of entries: 1,024 files **HEMO** List: Number of entries: 1 024 files

Full Disclosure: Storage time: Up to 72 hours

Number of Waveforms stored: 5 maximum

ST Recall: Number of files: 4,320 files (1 per minute for 72 hours) for

all monitoring leads

Alarm History: Number of entries: 16,384 files Arrhythmia Recall: Number of files: 16,384 files

12-Lead

Interpretive Recall:

Number of files: 18 files

OCRG: Storage capacity: 72 hours

RECORDER (option)

Recording Method: Thermal array recording Number of Channels: 3 traces (maximum)

POWER REQUIREMENT

100 to 240 V ±10% AC:

Line Frequency:

50 or 60 Hz

Battery Operation

Time (option):

Up to 90 minutes

Power Consumption: AC 100 VA

DIMENSIONS AND WEIGHT

Dimensions:

370 W × 310 H × 172 D mm

Weight:

Smart Cable is a Trademark of Nihon Kohden Corporation. Different Thinking for Better Healthcare is a registered trademark of Nihon Kohden.

